SUPREME COURT, U.S.
NOV 13 1974
MICHAEL RODAK, JR., CLERK

IN THE

Supreme Court of the United States

October Term 1974

No. 74-574

NATIONAL NUTRITIONAL FOODS ASSOCIATION, SOLGAR CO., INC., and NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS,

Petitioners,

against

FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH, EDUCATION AND WELFARE,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH, EDUCATION AND WELFARE,

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Petitioners pray that a writ of *certiorari* issue to review the judgment of the United States Court of Appeals for the Second Circuit, entered in the above-entitled proceeding on August 15, 1974.

Citations to Opinions Below

The opinion of the Court of Appeals is set forth in Appendix A and has not yet been officially reported. An earlier opinion of the Court of Appeals dealing with a preliminary procedural issue is set forth in Appendix B and is officially reported at 491 F. 2d 1141 (2nd Cir. 1974).

Jurisdiction

The judgment of the Court of Appeals was entered on August 15, 1974. The jurisdiction of this Court is invoked under 28 U. S. C. §1254(1) and 21 U. S. C. §371(f)(4).

Questions Presented

1. Whether the Court of Appeals ruled contrary to the decisions of this Court by upholding the use of a standard of identity under §401 of the Federal Food, Drug, and Cosmetic Act [21 U. S. C. §341] to prohibit the industry-wide sale of numerous properly-labeled safe food products.

2. Whether the standard of identity provisions of §401 of the Federal Food, Drug, and Cosmetic Act can be used to regulate the quantity per unit of a food product, as distinguished from its identity.

3. Whether §403(a) of the Federal Food, Drug, and Cosmetic Act authorizes the issuance of prepublication prohibitions on food labeling statements which deprive affected parties of the right to show, in a given context, that such statements are not false or misleading and which alter the statutory burden of proof.

4. Whether the rule of law established by this Court in *Morgan* v. *United States*, 298 U. S. 468 (1936) is still viable so as to allow a challenge to the promulgation of orders based on an evidentiary public hearing on the basis of a strong showing that the administrative officer responsible for such orders did not comply with his duty to personally "consider and appraise" the record and objections before him prior to affixing his signature to such orders.

Statutes and Regulations Involved

Statutory provisions of the Federal Food, Drug, and Cosmetic Act involved herein are §§401, 403(a), (c), (g), (h), (i) and (j), 701(a), (e) and (f) [21 U. S. C. §§341, 343(a), (c), (g), (h), (i) and (j), 371(a), (e) and (f)] which are set forth in Appendix C. The regulations which are at issue herein are proposed additions to Title 21 of the Code of Federal Regulations, 21 C. F. R. §§125 and 80.1. They are printed in Appendix D.

Statement

The regulations which are the subject of this petition are the end-product of a twelve year effort by the Food and Drug Administration to drastically alter the marketing structure and status of vitamin and mineral products in the United States. The detailed and complex nature and interrelationship of these regulations are set forth at some length in the Opinion of the Court of Appeals (Appendix A, A5-A13). Briefly, the regulations establish restrictions and limitations on vitamin and mineral products under the purported statutory authority for standards of identity (§80.1, Appendix D, D4-D7). In addition, the regulations impose unprecedented prepublication prohibitions against the making of various statements in the labeling of foods for special dietary use, employing a lesser burden of proof than that which would otherwise obtain under the statute (§125.2(b), Appendix D, D1-D3).

The Court of Appeals, with modifications, upheld the standards of identity and the prohibitions on labeling statements. The Court of Appeals stayed the regulations for the purpose of agency consideration of various ex-

ceptions to the standards of identity and directed the agency to revise the regulations in certain respects not at issue herein. These extensive and complex regulations were signed by the Commissioner of Food and Drugs only 13 days after he was installed as commissioner.

The jurisdiction of the Court of Appeals in this matter was based on §701(f) of the Federal Food, Drug, and Cosmetic Act [21 U. S. C. §371(f), Appendix C, C8-C9]. By virtue of §701(f)(4) the judgment of the Court of Appeals "affirming or setting aside in whole or in part" is "final" and subject to review by this Court by way of the instant petition for a writ of certiorari (Appendix C, C9).

Reasons for Granting the Writ

Petitioners respectfully submit that *certiorari* should be granted herein to resolve important and recurring questions basic to the implementation of the Federal Food, Drug, and Cosmetic Act affecting the entire food and dietary supplement industry in this country. The opinion of the Court of Appeals is contrary to the express decisions of this Court with respect to statutory construction of the extent of agency authority under the Federal Food, Drug, and Cosmetic Act. This proceeding also presents a clear factual picture for resolution of the application of the *Morgan* decisions of this Court to the procedural decision making process of all administrative agencies.

Petitioners seek to resolve the interpretation and distinction between various long-standing decisions of this Court which in one instance have received contrary interpretations by two United States Courts of Appeals. In addition, the Court is presented with important questions as to agency authority and jurisdiction to prohibit the making of label statements without a factual finding

that such statements are false or misleading in a given context.

I. The central thrust of the vitamin regulations is to establish an agency-imposed conformity in the manufacture and sale of dietary food supplements. First, the regulations [§80.1(a)] give a broad definition to the term "dietary supplement" so as to include every product sold for its vitamin or mineral content. Secondly, the regulations expressly state that only four specific combinations of dietary supplements comprising more than one vitamin or mineral may be sold. The Court of Appeals held that by setting up a standard of "identity," the agency has the authority to totally ban from the marketplace combinations and potencies of vitamins and minerals other than those on the approved list.*

As acknowledged by the Court of Appeals, the legislative history of §401 of the Act expressly shows that Congress intended the opposite result (Appendix A, A31):

> "It should be noted that the operation of this provision will in no way interfere with the marketing of any food which is wholesome but which does not meet the definition and standard . . ." Senate Report No. 361, 74th Cong., 1st Sess. (1935), in Dunn, The Federal Food, Drug, and Cosmetic Act, page 246 (1938).

This legislative intent is inherent in the enforcement provision of §403(g) of the Act [21 U. S. C. §343(g)] which

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* The only exception held out by the Court of Appeals is the possible sale of "imitation dietary supplements." The Court of Appeals noted that sale of products in accordance with this "concession" by FDA counsel might insure the products' unacceptability to the public (Appendix A, A28). With respect to the unreasonableness of imposing such destructive labeling, see *Nolan* v. *Morgan*, 69 F. 2d 471 at 474 (7th Cir. 1934).

provides that a food is deemed misbranded "if it *purports to be or is represented* as a food for which a definition and standard of identity has been prescribed by regulations as provided by §401, unless (1) it conforms to such definition and standard . . ." (emphasis added). For example, a vitamin C and E combination product, which is not included on the approved FDA list, could easily be labeled so that it does not "purport" to be or "represent" itself as being the standardized all-inclusive "multivitamin or mineral" supplements.* Yet the regulations seek to flatly prohibit any nonconforming sale. See §§80.1(b)(1) and 125.2(b)(5) of the proposed regulations, Appendix D, D3 and D4.

The Court of Appeals decision, upholding the total ban on nonstandard products,** contrary to the statutory language and legislative history, is based exclusively on its erroneous interpretation of this Court's decision in *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U. S. 218 (1943).

The basic error of the Court of Appeals herein is that when a standard of identity was established for farina, it did not thereby ban the sale of any cereal products which did not use the word, or purport to be the standardized farina. In *Quaker Oats*, a leading cereal company was challenging the standard because it did not wish to inform the public on its labeling that its product did not comply with the standard for Farina or Enriched Farina.

In fact, the agency's interpretation of *Quaker Oats* as adopted by the Court of Appeals, was expressly rejected by this Court in *62 Cases of Jam* v. *United States*, 340

* In fact under §403(j) of the Act [21 U. S. C. §343(j)], the agency has the authority to prescribe specific label statements to ensure such a distinction.

** As hereinabove noted, the Court of Appeals left open the question of possible sale as imitation vitamin products.

U. S. 593 (1951). The question presented in the *Jam* case was whether the product "purported" to be the food for which a standard had been established. The Court held with respect to a product clearly labeled "imitation jam":

> "We see no justification to distort the ordinary meaning of the statute. . . . In §403(g) Congress used the words 'purport' and 'represent'—terms suggesting the idea of counterfeit. But the name 'imitation jam' at once connotes precisely what the product is: a different, an inferior preserve, not meeting the defined specifications . . . a product so labeled is described with precise accuracy. It neither conveys any ambiguity nor emanates any untrue innuendo. . . . It purports and is represented to be only what it is—an imitation. It does not purport nor represent to be what it is not—the Administrator's genuine 'jam.'
>
> In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop. The Government would have us hold that when the Administrator standardizes the ingredients of a food, no imitation of that food can be marketed which contains an ingredient of the original and serves a similar purpose. If Congress wishes to say that nothing shall be marketed in likeness to a food as defined by the Administrator, though it is accurately labeled, entirely wholesome, and perhaps more within the reach of the meager purse, our decisions indicate that Congress may well do so. But Congress has not said so. It indicated the contrary. Indeed, the Administrator's contemporaneous construction concededly is contrary to what he now contends. We

must assume his present misconception results from a misreading of what was written in the Quaker Oats Case." *Id.* at 340 U. S. 600-601.

The Court of Appeals, however, improperly restricted the scope of the *Jam* case as being limited solely to "imitation" products. In that case, imitation jam was an appropriate way to distinguish the nonstandard product and still use the word "jam." Here, other terms could be used to accomplish such distinction, thereby allowing the continued sale of nonconforming products in accordance with the clear intent of the statute. If the Court of Appeals' holding herein is allowed to stand, the agency will in effect have the authority *to move into any food area where product differentiation has developed and so define and standardize the class as to drive long-established products from the marketplace.* No such drastic power was ever granted to the agency and petitioners respectfully submit that a writ of *certiorari* should issue to review this grant of power to the agency by the Court of Appeals.

II. Petitioners submit that the standard of identity provisions of §401 of the Federal Food, Drug, and Cosmetic Act cannot be used to regulate the quantity per unit of a food product, as distinguished from its identity. The Court of Appeals herein upheld agency restrictions on the sale of individual vitamins or minerals in terms of the *quantity* sold. See §80.1(b)(2), Appendix D, D4. The identity of each vitamin or mineral, however, has long been established and the regulations include charts specifying the chemical composition of various vitamins (Appendix D, D2 and D7).

Given such an established identity, there is no authority or basis under §401 of the Act for restricting the amount of a given vitamin or mineral which can be sold. For example, vitamin C has the same "identity" whether it is

sold in quantities of 50, 100 or 500 milligrams. The agency's restrictions on quantity relates to its opinion as to the estimated amounts of vitamins and minerals which are needed for the average person's daily diet. Although the Court of Appeals rejected the criteria used by the agency, it did not remove the basic question of statutory construction here in issue.

Public protection relative to the quantitative usefulness of "foods for special dietary use" is specifically covered by §403(j) of the Act [21 U. S. C. §343(j), Appendix C, C6], which requires informative labeling so as to "fully inform the purchaser as to its value for such uses." The use of §401 in the instant regulation is contrary to the legislative purpose and intent for the establishment of standards of "identity."

III. The instant regulations prohibit the making of certain statements on the labeling of foods for special dietary use. In addition, statements which *suggest* or *imply* the prohibited statements are also barred (§125.2(b), Appendix D, D2-D3). The Court of Appeals held (Appendix A, A70) that these prohibitions are authorized by §403(a) of the Act [21 U. S. C. §343(a), Appendix C, C3] which deems misbranded any food product whose labeling is false or misleading in any particular. Misbranded products in turn are subject to severe civil and criminal sanctions, e.g., 21 U. S. C. §331.

The Court of Appeals erred herein in the following respects:

(a) The agency does not have the power to issue substantive regulations under §403(a) of the Act. The power of the agency to issue substantive regulations under §701(e) of the Act, [21 U. S. C. §371(e), Appendix C, C7-C8] is limited to the implementation of specific statu-

tory sections listed therein.* Section 403(a) of the Act is not listed in §701(e). Similarly, the jurisdiction of the Court of Appeals in this proceeding under §701(f) of the Act, [21 U. S. C. §371(f)] is limited to regulations promulgated under §701(e) of the Act. The Court of Appeals permitted the agency to include these regulations in a §701(e) proceeding, by a novel theory akin to pendant jurisdiction (Appendix A, A15).

Petitioners submit that there is no precedent or legal basis for this invocation of pendant jurisdiction in a Court of Appeals. The actual effect of this ruling is to give the administrative agency the legislative power to add further statutory sections to those specifically enumerated by Congress in §701(e) of the Act. A further material and prejudicial effect of the Court of Appeals ruling is to give the administrative agency the power, at its option, to transform interpretive regulations into substantive regulations.

(b) The agency cannot decree general prepublication prohibitions of statements or implications as false or misleading under §403(a), as distinguished from a consideration of the actual statements in their actual context. For example, §125.2(b)(5) (Appendix D, D3), states that certain food ingredients, such as rutin, have not been shown to be essential in human nutrition. The regulation then decrees in §125.2(b)(5)(ii) that it would be false or misleading to state or imply in the labeling for rutin that such ingredient has no nutritional or dietary value. Thus, a manufacturer selling rutin is subject to criminal sanctions if in the future he states or implies that it has no nutritional or dietary value, despite the fact that this is the very finding of fact made by the agency in this pro-

* The agency can issue *interpretive* regulations with respect to §403(a) pursuant to §701(a) of the Act.

ceeding. This Orwellian *reductio ad absurdum* of the regulations illuminates the impropriety of the agency's regulatory approach.

It is true that there may be circumstances where disclaimers of nutritional value may be misleading in a given context. However, inherent in the agency's attempted prohibitions is the premise that the English language cannot be used to properly inform the consumer as to the value or usefulness of the product as directed by §403(j) of the Act.

(c) The agency does not have the power to alter its statutory burden of proof under §403(a) of the Act, but must seek any such change from Congress. Petitioners' rights have clearly been prejudiced by the ruling of the Court of Appeals herein. Any regulations in connection with §403(a) can only be interpretive, thus permitting a factual finding in enforcement proceedings that the labeling in question is not false or misleading. In any such enforcement proceeding, the burden on the government would be to prove labeling false or misleading by either a preponderance of the evidence in a civil case, or beyond a reasonable doubt in a criminal case. By permitting the agency to incorporate a regulation under §403(a) in a §701(e) proceeding, the agency's burden of proof is reduced to a showing of substantial evidence in the administrative record.

Petitioners respectfully submit that this Court should review the unprecedented assumption of jurisdiction herein which has the equally unprecedented effect of prohibiting label statements even though they are not false and misleading in a given context.

IV. The record in the administrative proceeding herein consists of 32,000 pages of testimony, thousands of pages

of documentary exhibits, a lengthy report by the hearing examiner, and over 1000 pages of formal objections and exceptions. The Commissioner of Food and Drugs herein assumed his office on July 12, 1973. Thirteen days later, he affixed his signature to the extensive and complex regulations which are the subject of the instant proceeding. Based on the information presently available to petitioners, which was presented to the lower court, during this 13-day period (which included two weekends), the newly appointed Commissioner signed and caused to be published fourteen final regulations, thirteen proposed regulations, and six notices.

This proceeding involves regulations making factual determinations required by statute to be based solely on substantial evidence adduced at a public hearing with the "actual decision" to be made by the Commissioner of Food and Drugs. *Willapoint Oysters* v. *Ewing*, 174 F. 2d 676 at 696 (9th Cir. 1949), 21 U. S. C. §371(e), 21 C. F. R. 2.98. The nature of the personal duty was spelled out by this Court in *Morgan* v. *United States*, 298 U. S. 468 (1936) [*Morgan I*] which required the responsible officer to personally "consider and appraise" the evidence and argument. *Id.* at 480-482.

The Court of Appeals herein agreed that under this Court's ruling in *Morgan I*, petitioners would be entitled to take the deposition of the Commissioner to show under the circumstances of this case that the Commissioner had not complied with his duty (Appendix B, B6). The lower court denied petitioners' application for discovery and ruled that the decision of this Court in *United States* v. *Morgan*, 313 U. S. 409 (1941) [*Morgan IV*] involved a "retreat" from the principles established in *Morgan I*. The Court of Appeals ruled that absent "the most powerful preliminary showing to the contrary," the Courts

were required to presume that the Commissioner had complied with his duty (Appendix B, B10).

The ruling of the Court of Appeals as to the continued viability of *Morgan I* under the circumstances of this case, is contrary to the decision of the Fourth Circuit in *Singer* v. *NLRB*, 329 F. 2d 200, 206-208 (4th Cir., 1964) and also to the subsequent decision of the Second Circuit in *KFC National Management Corp.* v. *NLRB*, 497 F. 2d 298, 303-306 (2nd Cir. 1974). Both of these cases clearly hold that *Morgan IV* did not signify a retreat from *Morgan I*, but merely re-emphasized the threshold requirements of an appropriate showing before an inquiry was made into the administrative decision-making process.

In this case the Court of Appeals agreed that circumstances surrounding the promulgation of the regulations presented a "situation where two unusual and indisputable facts, namely, the short time between Commissioner Schmidt's assumption of office and his signing the regulations here at issue, and the large number of other rules promulgated by him in the interval, create more than ordinary bases for doubt as to the extent of his personal reading and consideration" (Appendix B, B5-B6) 491 F. 2d at 1144. Petitioners respectfully submit that these facts constitute a "strong showing of improper behavior" in line with the threshold requirements indicated by this Court in *Citizens to Preserve Overton Park* v. *Volpe*, 401 U. S. 402 at 420 (1971). See also *United States ex rel. Accardi* v. *Shaughnessy*, 347 U. S. 260 (1954) and *Shaughnessy* v. *United States ex rel. Accardi*, 349 U. S. 280 (1955).

Petitioners respectfully submit that a writ of *certiorari* should issue to review the lower court's establishment of a virtually irrebuttable presumption of regularity which is contrary to the decisions of this Court. This issue is now particularly urgent in light of the partial remand directed by the lower court. There is a serious danger that the

substantially reduced requirements for personal action on the part of the Commissioner may be applied.

This issue, between the parties herein, as to the lower court's error with respect to *Morgan I* was recently presented to this Court by way of a petition for a writ of *certiorari* under Docket No. 73-1700. That petition, however, also included an issue as to the jurisdiction of the district courts to entertain challenges to the Commissioner's action under the Federal Food, Drug, and Cosmetic Act. The opposition brief submitted by the Solicitor General took the position that only the jurisdictional issue was ripe at that time and therefore did not discuss the substantive issue, as raised herein. The earlier petition for a writ of *certiorari* was denied by this Court on October 15, 1974 (Mr. Justice Douglas would have granted *certiorari*). The issue is now ripe for determination as part of a general petition with respect to the Court of Appeals decision on the merits herein.

The interest of justice herein and the public interest in further responsible administrative decision-making in this matter, as well as by all administrative agencies, warrant a reaffirmation by this Court of the principles established in *Morgan I*.

CONCLUSION

For the foregoing reasons, this petition for a writ of *certiorari* should be granted.

Respectfully submitted,

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ROBERT ULLMAN,
SHELDON S. LUSTIGMAN,
Counsel for Petitioners.

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APPENDIX TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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APPENDIX A

OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT (AUGUST 15, 1974)

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

Nos. 1189-1203—September Term, 1973.

(Argued June 19, 1974 Decided August 15, 1974.)

Docket Nos. 73-2129, 73-2166, 73-2175, 73-2449, 73-2745, 73-2746, 73-2747, 73-2748, 73-2752, 73-2753, 73-2762, 73-2824, 73-2826, 73-2834, 74-1055

NATIONAL NUTRITIONAL FOODS ASSOCIATION AND SOLGAR COMPANY, INC., et al.,

Petitioners,

v.

FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, et al.,

Respondents.

Before:

FRIENDLY and SMITH, *Circuit Judges,* and BARTELS, *District Judge.**

Petitions to review final regulations of the Food and Drug Administration fixing standards of identity for and

* Of the District Court for the Eastern District of New York, sitting by designation.

prescribing label statements concerning food for special dietary uses.

Petitions granted in part and denied in part, regulations stayed, and cause remanded.

MILTON A. BASS, Esq., New York, N. Y. (Bass & Ullman, New York, N. Y., of Counsel), *for Petitioners National Nutritional Foods Association, Solgar Co., Inc., and National Association of Pharmaceutical Manufacturers.*

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DANIEL MARCUS, Esq., Washington, D.C. (Wilmer, Cutler & Pickering, Richard A. Allen, Esq., and Daniel D. Polsby, Esq., Washington, D.C., of Counsel), *for Petitioners Archon Pure Products Corp., Plus Products, Wm. T. Thompson Company, and Council for Responsible Nutrition.*

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Appendix A

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EDGAR T. BELLINGER, Esq., Washington, D.C. (Pope, Ballard & Loos and Dickson R. Loos, Esq., Washington, D.C., of Counsel), *for Petitioner Sunkist Growers, Inc.*

JOHN JOSEPH MATONIS, Esq., Washington, D.C., *for Petitioners Citizens for Truth in Nutrition, Catharyn Elwood, and East Coast Healthfood Organization.*

MICHAEL R. SONNENREICH, Esq., Washington, D.C. (Chayet and Sonnenreich, and Michael X. Morrell, Esq., Washington, D.C., of Counsel, Department of Health, Education *Ph.D., and Roger J. Williams, Ph.D.*

HOWARD S. EPSTEIN, Esq., Antitrust Division Department of Justice, Washington, D.C.; STEPHEN H. MCNAMARA, Esq., and HOWARD M. HOLSTEIN, Esq., Office of the General Counsel, Department of Health Education and Welfare, Washington, D.C.; GREGORY B. HOVENDON, Esq., Chief, Consumer Affairs Section, Department of Justice, Washington, D.C. (Thomas E. Kauper, Assistant Attorney General, Antitrust Division, Department of Justice, Washington, D.C., and Richard A. Shupack, Esq., Office of General Counsel, Department of Health, Education and Welfare, Washington, D.C., of Counsel), *for Respondents Food and*

Appendix A

Drug Administration, United States Department of Health, Education and Welfare, et al.

FRIENDLY, *Circuit Judge*:

We have here 15 petitions under § 701(f) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 371(f), to review two final regulations of the United States Food and Drug Administration (FDA)[1] relating to vitamin and mineral supplements sold as foods. One regulation, entitled Part 125—Label Statements Concerning Dietary Properties of Food Purporting To Be Or Represented For Special Dietary Uses, would replace corresponding parts of an existing regulation issued in 1955, 21 C.F.R. Pt. 125. The other, entitled Part 80—Definitions And Standards Of Identity For Food For Special Dietary Uses, embodies a new concept in regard to this type of "food."[2] Both were published in the Federal Register of August 2, 1973, 38 F.R. 20708-18, 20730-40, to become fully effective January

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1 Four petitions were filed in this circuit. On the representation of the FDA that petitions had been earlier filed in the Ninth Circuit, we transferred the petitions to that circuit, 28 U.S.C. § 2112(a), without prejudice to a motion to retransfer. The Ninth Circuit granted such a motion and also transferred the six petitions that had been filed there. Five petitions later filed in the District of Columbia Circuit were transferred here.

We have previously denied a motion by some of the petitioners to take the testimony of the Commissioner of Food and Drugs to determine the extent of his familiarity with the regulations and for related relief, or for the appointment of a special master to achieve similar ends, *National Nutritional Foods Ass'n* v. *FDA*, 491 F.2d 1141 (2 Cir. 1974).

2 Neither regulation entirely conforms to its title. The Label Regulation contains at least two controversial substantive provisions, § 125.1(c) and (h), *see also* § 125.2(b)(5), discussed at pp. 5282-5283 *infra*, and the Standard of Identity Regulation contains various label requirements, including at least § 80.1(d) and (h) through (m).

1, 1975. The primary statutory authority invoked for the Regulations lies in the first sentence of § 401:

> Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container.

21 U.S.C. § 341, and in § 403, which provides *inter alia* that a food shall be deemed to be misbranded

> (j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

21 U.S.C. § 343(j).

The proceedings which culminated in these regulations began with a Notice of Proposal To Revise Regulations published in the Federal Register of June 20, 1962, 27 F.R. 5815. Extensive revisions were made in response to comments, but numerous parties filed objections to the proposed revised regulations and requests for a hearing pursuant to § 701(e)(2), 21 U.S.C. § 371(e)(2). The proposed regulations were accordingly stayed for an evidentiary hearing under § 701(e)(3), 21 U.S.C. § 371(e)(3). This lasted for more than 22 months and developed a transcript of 32,405 pages, together with hundreds of exhibits and other record materials. In the Federal Register of January 19, 1973,

the FDA published proposed findings and conclusions and tentative versions of the regulations for a final round of exceptions and comments, 38 F.R. 2143 (1973). After considering these, the agency promulgated the final regulations.

As indicated, the novelty of the regulations lies in the FDA's invoking, with respect to the many vitamins and minerals and the myriad combinations thereof, its power to prescribe a standard of identity under § 401. The new Part 80 begins, § 80.1(a), by describing as its object "dietary supplements of vitamins and/or minerals" which "purport to be or are represented for special dietary use by man to supplement his diet by increasing the total dietary intake of one or more of the essential vitamins and/or minerals specified in paragraph (f) of this section." The regulation then goes on as follows:

> (b) Classifications of dietary supplements.
>
> (1) A dietary supplement shall contain only those vitamins and/or minerals listed in paragraph (f) of this section and shall be offered for its vitamin and/or mineral content only in the following combinations, with the provision that any vitamin or mineral defined as optional in paragraph (f) of this section may be omitted:
>
> (i) All vitamins and minerals.
>
> (ii) All vitamins.
>
> (iii) All minerals.
>
> (iv) All vitamins and the mineral iron.
>
> (v) Inclusion of the optional ingredients vitamin D and/or phosphorus in a multivitamin, multimineral, or multivitamin and multimineral supplement does not require inclusion of any additional optional ingredi-

ents. Inclusion of the optional ingredients biotin and pantothenic acid and/or copper and zinc in such products does not require inclusion of vitamin D and/or phosphorus when the latter two nutrients are optional. The inclusion of any of the other optional ingredients (biotin or pantothenic acid for vitamins and copper or zinc for minerals) requires the inclusion of both such optional ingredients if the product is a multivitamin or multimineral supplement, and requires the inclusion of all four such ingredients if the product is a multivitamin and multimineral supplement.

(2) A dietary supplement may also be composed of any single vitamin or mineral listed in paragraph (f) of this section.

Before going further it is necessary to refer to another major innovation in the regulations. The previous regulation had required, 21 C.F.R. § 125.3(a)(1) and (2), § 125.4 (a)(1) and (2), that in the case of certain vitamins and minerals the label of a food represented for special dietary use should disclose the percentage of the designated "minimum daily requirement" which would be "supplied by such food when consumed in a specified quantity during a period of one day"; for other vitamins and minerals the requirement was merely that the label state the quantity of the nutrient contained in a specified quantity of such food. The regulations here under challenge substituted for "minimum daily requirements" a new concept of "U.S. Recommended Daily Allowances."[3] These are stated, § 80.1(f)(2), to have been derived by the FDA from the Recommended Dietary Allowances published by the Food and Nutrition Board, National Academy of Sciences—National Research Council, and to be "subject to amendment from time to time as more information on human nutrition becomes available."

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3 *See* note 4 *infra*.

Appendix A

Section 80.1(f)(1) sets forth "the permissible qualitative and quantitative composition of dietary supplements of vitamins and/or minerals" in the form of a table, as follows:

U.S. GOVERNMENT RECOMMENDED DAILY ALLOWANCES (U.S. RDA's) AND PERMISSIBLE COMPOSITIONAL RANGES FOR DIETARY SUPPLEMENTS OF VITAMINS AND MINERALS

	Unit of Measurement	Children under 4 years of age [1]—U.S. RDA		Adults and children 4 or more years of age—U.S. RDA		Pregnant or lactating women—U.S. RDA	
		Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
Vitamins							
Mandatory							
Vitamin A	International Units	1,250	2,500	2,500	5,000	5,000	8,000
Vitamin D [2]	do	200	400	400		400	400
Vitamin E	do	5	10	15	30	30	60
Vitamin C	Milligrams	20	40	60	90	60	120
Folic acid [3]	do	0.1	0.2	0.3	0.4	0.4	0.8
Thiamine	do	0.35	0.70	1.05	0.75	1.50	2.25	1.50	1.70	3.00
Riboflavin	do	0.4	0.8	1.2	0.8	1.7	2.6	1.7	2.0	3.4
Niacin	do	4.5	9.0	13.5	10.0	20.0	30.0	20.0	20.0	40.0
Vitamin B6	do	0.35	0.70	1.05	1.00	2.00	3.00	2.00	2.50	4.00
Vitamin B12	Micrograms	1.5	3.0	4.5	3.0	6.0	9.0	6.0	8.0	12.0
Optional							
Vitamin D	International Units				200	400	400			
Biotin [4]	Milligrams	0.075	0.150	0.225	0.150	0.300	0.450	0.300	0.300	0.600
Pantothenic acid	do	2.5	5.0	7.5	5.0	10.0	15.0	10.0	10.0	20.0
Minerals Mandatory							
Calcium	Grams	0.125	0.800	1.200	0.125	1.000	1.500	0.125	1.300	2.000
Phosphorus [5]	Do	0.125	0.800	1.200	0.125	1.000	1.500			
Iodine	Micrograms	35	70	105	75	150	225	150	150	300
Iron	Milligrams	5	10	15	9	18	27	18	18	60
Magnesium	Do	40	200	300	100	400	600	100	450	800
Optional							
Phosphorus [5]	Grams							0.125	1.300	2.000
Copper	Milligrams	0.5	1.0	1.5	1.0	2.0	3.0	1.0	2.0	4.0
Zinc	Do	4.0	8.0	12.0	7.5	15.0	22.5	7.5	15.0	30.0

[1] When labeled for use by infants, a dietary supplement shall contain not less than the lower limit designated for a nutrient in this column nor more than 100% of the infant U.S. RDA for a nutrient as prescribed in §125.1(b) except that the level of biotin, when used, shall be 0.05 mg per daily recommended quantity.
[2] Optional for adults and children 4 or more years of age.
[3] Optional for liquid products.
[4] Lower limit may be 0.05 milligram until December 31, 1978.
[5] Optional for pregnant or lactating women. When present, the quantity of phosphorus may be no greater than the quantity of calcium.

Section 80.1(c) requires that dietary supplements contain in the quantity specified in the label for consumption in one day by each population group listed in the table not less than the lower nor more than the upper limits there listed.

Rounding out the picture, §§ 80.1(h)(1) and (2) prescribe:

(h) Nomenclature.

Appendix A

(1) The common name of a dietary supplement shall consist of a term descriptive of the vitamin and/or mineral composition of the product, as established in paragraph (h)(2) of this section, together with a phrase or phrases designating the group(s) for which the supplement is represented, as established in paragraph (h)(3) of this section (e.g., "multivitamin and multimineral supplement for children under 4 years of age"). The name of the dietary supplement shall appear prominently and conspicuously on the principal display panel(s) of the label. The letters of the phrase(s) designating the consumer group(s) for which the product is represented shall be no less than one-third the size of those used in the term descriptive of the composition of the product. In addition to the common name prescribed by this paragraph, a dietary supplement may be labeled with a proprietary name: *Provided,* That it is not false or misleading in any particular.

(2) The terms used to describe the vitamin and/or mineral composition of dietary supplements listed in paragraphs (b) (1) and (2) of this section shall be as follows: (i) "Multivitamin and multimineral supplement" for a dietary supplement containing all vitamins and minerals, (ii) "multivitamin supplement" for a dietary supplement containing all vitamins, (iii) "multimineral supplement" for a dietary supplement containing all minerals, (iv) "multivitamin and iron supplement" or "multivitamin supplement with iron" for a dietary supplement containing all vitamins and the mineral iron, (v) "———supplement" for a dietary supplement containing a single vitamin or mineral listed as a mandatory or optional ingredient in the table contained in paragraph (f)(1) of this section

(the blank to be filled in with the name of the vitamin or mineral).

Various exemptions are provided from the operation of Part 80, of which the most important are contained in § 80.1(b)(5):

> The provisions of this section shall not apply to any food which contains or consists of any vitamin or mineral listed in § 125.1(b) of this chapter [the same vitamins and minerals as those listed in the § 80.1(f)(1) table, *supra*], or any combination thereof, provided that all of the following requirements are met: (i) No such nutrient is contained at a level of 50 percent or more of the adult U.S. RDA per serving for that nutrient, (ii) No direct or implied representation is made on the label, in labeling, or in advertising that the product is a dietary supplement or is adequate or appropriate for supplementing the daily diet with essential nutrients, and (iii) The product is labeled pursuant to the provisions of § 1.17 of this chapter [relating to nutrition labeling of foods].

and § 80.1(e)(5)-(7):

> (5) Raw agricultural commodities (including marine products) and fabricated and other conventional foods to which single or multiple vitamins and/or minerals are added to improve nutritional quality, unless the total level (including any naturally occurring amounts) of any added vitamin or mineral per single serving attains or exceeds 50 percent of the U.S. Recommended Daily Allowance (U.S. RDA) for adults and children 4 years or more of age as specified in § 125.1(b) of this chapter, in which case the provisions of both this section and § 1.17 of this chapter shall apply. If the

provisions of both this section and § 1.17 apply to a food, the labeling of such food shall conform to the labeling established in this section except that the labeling established in paragraph (c) of § 1.17 of this chapter, including the order for listing vitamins and minerals established in paragraph (c)(7)(iv) of that section, shall be used in lieu of the labeling established in paragraph (i)(1) of this section.

(6) Raw agricultural commodities (including marine products) which by their nature are sources of a specific vitamin(s) and/or mineral(s) at a level that, if it had been added, would have brought them within the definition of a dietary supplement. Such shall meet all the requirements of this section if they are represented as dietary supplements. Such foods may also be used as a source of specific vitamins and/or minerals in dietary supplements meeting the requirements of this section.

(7) A food with nutrients restored to pre-processing levels or added pursuant to § 1.8(e) of this chapter so that it is not nutritionally inferior to the food for which it substitutes and which it resembles.

Finally, two provisions of § 125.1 are parts of this basic regulatory scheme. Starting with a reference to § 125.1(b), which sets out the same vitamins and minerals as listed in the table reproduced above along with the U.S. RDA's for the three classes of consumers there listed and a fourth class of "infants," [4] § 125.1(c) states:

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4 This tabulation in § 125.1(b) is incorporated by reference in § 125.3 (a), which requires that a food "represented to be for special dietary use because of vitamin or mineral properties" must "bear a statement of the percentage of the U.S. RDA of such vitamins and minerals, as set forth in § 125.1(b), supplied by such food when consumed in a specified quantity during a period of 1 day . . . . If such purported or

(c) In addition to the vitamins and minerals listed in paragraph (b) of this section, vitamin K, choline, and the minerals chlorine, potassium, sodium, sulfur, fluorine, and manganese are recognized as essential in human nutrition, but no U.S. Recommended Daily Allowance (U.S. RDA) has been established for these nutrients. These nutrients are not appropriate for addition to general purpose foods or dietary supplements of vitamins and minerals but may be added to such other foods for special dietary use as infant formulas, and foods represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions.

And § 125.1(h) states:

(h) Any product containing more than the upper limit of the U.S. RDA per serving (or where appropriate, per daily recommended quantity) of a vitamin or mineral as specified in § 80.1(f)(1) of this chapter is a drug, except for conventional foods which contain naturally-occurring amounts in excess of these limits or which contain added amounts in excess of these limits pursuant to § 1.8(e) of this chapter so that it is not nutritionally inferior to the food for which it substitutes and which it resembles, and except as provided for in a specific regulation for such special dietary foods as infant formulas or foods which are represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions.

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represented special dietary use is for persons within one or more groups for which the recommended daily allowance is set, such statement shall include the percentage for each age group."

It will be more convenient to defer description of other relevant provisions of the Regulations until subsequent discussion of them.

I. *Jurisdiction.*

We must first deal with the claim of National Nutritional Foods Association, Solgar Co., Inc., and National Association of Pharmaceutical Manufacturers that we lack jurisdiction to review eight provisions which these very petitioners have challenged. These are (1) § 80.1(b)(2), which has the effect of restricting the quantity of a single vitamin or mineral that may be sold in a dietary supplement; (2) § 80.1(b)(5), which exempts certain foods from the operation of § 80.1 if those foods are sold in servings not exceeding 50% of the U.S. RDA's and satisfy special label and labeling requirements; (3) the definition of "special dietary use" in § 125.1(a); (4) § 125.1(c), quoted above, which limits the inclusion of various nutrients for which RDA's have not been established; (5) § 125.2(a), which requires the principal display panel of the label of food for special dietary use to bear a statement of the usefulness of the food, a requirement which these petitioners consider, in light of one of the Commissioner's findings of fact (No. 3,38 F.R. 20713 (1973)), to have the effect of prohibiting the listing and thus the inclusion of certain types and amounts of ingredients; (6) § 125.2(b), which prohibits six categories of statements in the labeling (as distinguished from the label) of foods for special dietary use, as well as § 80.1(m), which incorporates by reference the label and labeling prohibitions contained in § 125.2(b); (7) § 125.2(b)(5), one of the six categories just mentioned, which prohibits the marketing of otherwise allowable foods for special dietary use if they contain ingredients the need for which in human nutrition has not been established; and (8) § 125.1(h), quoted above,

which, with some exceptions, classifies as a drug any product containing in one serving or in the daily recommended quantity more than the upper limit of the U.S. RDA's specified in the table.

The basis for the challenge to our power to review the eight provisions is this: The jurisdiction of a court of appeals under § 701(f) to review orders of the FDA is limited, so far as here pertinent, to orders promulgated under § 401, authorizing prescription of standards of identity, and § 403(j), authorizing the prescription of regulations concerning the labels of foods purporting to be or represented for special dietary uses.[5] A regulation issued under other sections, such as § 403(a), which deems a food "misbranded" if its labeling "is false or misleading in any particular," or § 701(a), the FDA's general authority "to promulgate regulations for the efficient enforcement" of the statute, must be challenged by an action in a district court. Compare *Gardner* v. *Toilet Goods Ass'n*, 387 U.S. 167 (1967), sustaining a suit in the district court attacking a general regulation promulgated under § 701(a) concerning color additives despite the availability of review of a decision refusing to approve a particular additive in a court of appeals by a combination of § 706(d), 21 U.S.C. § 376(d), and § 701(f). See also *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967). Any authority to promulgate the eight provisions, say these petitioners, must have arisen from sections of the Act other than §§ 401 or 403(j).

Petitioners' argument in the main confuses the question of jurisdiction with the merits. If the Commissioner rested

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5 Section 701(f)(1) permits any person who will be adversely affected by an order of the FDA promulgated under § 701(e) to petition the court of appeals for judicial review of the order. Section 701(e) sets out elaborate procedural requirements for issuing, amending, or repealing any regulation promulgated under § 401, § 403(j), and five other provisions of the Act not here pertinent.

his action on an arguable interpretation of §§ 401 or 403(j), our jurisdiction is not defeated by the possibility, even the probability, that we may ultimately reject his interpretation. As Mr. Justice Black pointed out in *Bell* v. *Hood,* 327 U.S. 678, 682-83 (1946), such a decision would be an exercise of jurisdiction, not a refusal to exercise it. And the case would not stand differently if, having rejected the Commissioner's position under the cited sections, we should find his action sustainable under others. Having acquired jurisdiction on the basis of the Commissioner's arguable invocation of §§ 401 or 403(j), we would be bound to decide the case as required by law. The situation is *a fortiori* to that where a federal court, having acquired jurisdiction of a suit challenging state action under 28 U.S.C. § 1343(3) because of a substantial constitutional claim, may decide pendent statutory claims over which it might not otherwise have jurisdiction because of lack of the required jurisdictional amount. See *Rosado* v. *Wyman,* 397 U.S. 397 (1970); *Hagans* v. *Lavine,* —— U.S. ——, 39 L.Ed.2d 577 (1974); *Almenares* v. *Wyman,* 453 F.2d 1075 (2 Cir. 1971), *cert. denied,* 405 U.S. 944 (1972).

With the possible exception of § 125.1(h), all the provisions, review of which is claimed to lie outside our jurisdiction, were rested at least in part on §§ 401 or 403(j). At this stage mere statement is practically sufficient to show that the FDA's position was fairly arguable,[6] as

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[6] Sections 80.1(b)(2) and 80.1(b)(5) were clearly rested on the FDA's authority to set standards of identity, § 401. Section 125.1(e), while included in Part 125, which deals generally with labels, and indeed in a subsection of Part 125, § 125.1, entitled "definitions and interpretations of terms," nevertheless is more akin to the provisions in Part 80 setting standards of identity and may therefore be said to arise under § 401. *See* note 2 *supra.*

Section 125.2(a) has every external indicium of having been promulgated under the FDA's authority to prescribe labels for foods purporting to be or represented for special dietary use, § 403(j). While §§ 125.2(b)

our subsequent discussion will demonstrate in greater detail. If § 125.1(h) stood alone, it would seem indeed that this was a regulation issued under the general rulemaking authority of § 701(a), interpreting the term "drug" in § 201(g)(1)(B), 21 U.S.C. § 321(g)(1)(B),[7] and that the petition to review should be dismissed as was done in an unreported order, *Citizens for Truth in Nutrition* v. *Food and Drug Administration*, No. 73-2826 (2 Cir., Mar. 4, 1974), where the court dismissed a petition to review an interpretive regulation issued under § 701(a), 21 C.F.R. § 3.94 and 3.95, requiring that preparations of vitamins A and D in dosages in excess of 10,000 and 400 international units, respectively, should be restricted to sale as "prescription drugs" under § 503(b)(1)(B), 21 U.S.C. § 353(b)(1)(B), and labeled accordingly. See *National Nutritional Foods Ass'n* v. *Weinberger*, 366 F. Supp. 1341, 1343-44 (S.D.N.Y.) [denial of temporary injunction], *aff'd*, 491 F.2d 845 (2 Cir. 1973), —— F. Supp. —— (S.D.N.Y. 1974) [dismissal of complaint], appeal pending. But here the provision stands as an integral part of a regulation colorably alleged to rest on §§ 401 and 403(j). The same important policy considerations of economy in judicial time which underly the doctrine of "pendent jurisdiction" as viewed in other contexts apply

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and 125.2(b)(5) deal with "labeling" and § 403(j) in terms is limited to "labels" (a narrower category, *see* p. 5274 *infra*), nevertheless the FDA made clear that it was relying in part on § 403(j) as authority. *See* 38 F.R. 20710 (1973) (final order), 38 F.R. 2149 (1973) (tentative final order), 31 F.R. 15730 (1966) (order staying the effective date of the regulations). Since, as we note later, the FDA's assertion of authority to promulgate these two provisions under § 403(j) has some force, our jurisdiction is clear.

7 The FDA unequivocally states that in promulgating § 125.1(h) it is giving content to § 503(b)(1)(B) of the Act, 38 F.R. 20710 (1973), and that it regards its actions in this regard as essentially interpretive under its authority in § 701(a) to promulgate regulations for the efficient enforcement of the Act. Brief for Respondents at 62.

a fortiori when the issue is whether a federal court of appeals with clear jurisdiction to review almost all provisions of a comprehensive set of regulations should finish the job or relegate a single provision to suit in a federal district court, possibly in another circuit, whose decision, of course, would be subject to appeal to a court of appeals.[8]

We hold that we have jurisdiction to consider all issues tendered.[9]

II. *Standards of Identity.*

The hardest issues in the case are (1) whether the FDA has power to set standards of identity for dietary supplements in such a way that vitamin and mineral products containing vitamins and/or minerals in nonstandardized combinations or whose daily dosage of any nutrient as specified in their labels exceeds the upper limit of the

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8 It is clear that petitioners are not prejudiced by this court's review under § 701(f). Since this court deems § 125.1(h) to be an integral part of the regulatory scheme under review, it is subjecting that provision to the standard of review specified in § 701(f)(2), substantial evidence. If the FDA had promulgated § 125.1(h) in ordinary rulemaking outside the § 701(e) proceeding, review before a district court would have been on the basis of the less demanding standard of 5 U.S.C. §§ 706(2)(A)-(E).

Our ruling is in no way inconsistent with the unreported order of the court in *Citizens for Truth in Nutrition* v. *Food and Drug Administration*, No. 73-2826 (2 Cir., Mar. 4, 1974), *supra*, dismissing a petition to review a wholly separate interpretive regulation which had already become the subject of a suit for an injunction in the district court.

9 The entire subject of the division of responsibility for review of agency action between the courts of appeals and the district courts is badly in need of study. See, with respect to the SEC, the splendid opinions of Chief Judge Seitz and Judge Adams in *PBW Stock Exchange, Inc.* v. *SEC*, 485 F.2d 718 (3 Cir. 1973), *cert. denied*, 42 U.S. L.W. 3610 (U.S., April 9, 1974), and ALI, Federal Securities Code, Tent. Draft No. 3 (April 1, 1974) § 1514(a) and Comment at pp. 88-89. It may well be that in some respects the jurisdiction of the courts of appeals should be expanded, whereas in others the ruling of the district court should be subject only to discretionary review.

U.S. RDA's[10] will be deemed misbranded under § 403(g), 21 U.S.C. § 343(g), *see* p. 16 *infra*, if they are offered for sale as foods; and, if so, (2) whether there was substantial evidence to support what the agency did. In this part of the opinion we shall deal with the issues generally, deferring to Part IV more detailed discussion of the evidentiary question with respect to the quantitative limits.

We should make clear at the outset that we do not at all join in the vituperation showered on the FDA by some of the petitioners.[11] Confronted with a difficult problem, the agency developed an innovative solution.[12] The questions for us are whether, giving the agency full credit for good intentions and according appropriate weight to its expertise, its action was within the powers that Congress has chosen to confer and is supported by substantial evidence. The conflicting considerations are neatly framed in two opinions of Mr. Justice Frankfurter. Writing of both the Food and Drugs Act of 1906 and the Food, Drug and Cosmetic Act of 1938 in *United States* v. *Dotterweich*, 320 U.S. 277, 280 (1943), he said:

> The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated

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10 No serious or specific objection appears to have been raised to the setting of lower limits—an objective clearly within the purpose and language of § 401.

11 The attacks based on the First Amendment and other constitutional grounds are not sufficiently substantial to warrant discussion.

12 Our respect for the agency's initiative, however does not extend to its drafting. The confused organization and wording of many parts of the regulations, and the rather careless marshalling of evidence to support even some findings of fact for which ample supporting evidence was available, have made this case considerably more difficult for all concerned than it had to be.

> as a working instrument of government and not merely as a collection of English words.

But eight years later he warned in *62 Cases of Jam* v. *United States*, 340 U.S. 593, 600 (1951):

> In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.

We begin by rejecting the argument of some petitioners that the FDA could not proceed simultaneously under §§ 401 and 403(j). Section 403(g) says that a food shall be deemed misbranded:

> If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341 of this title, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

21 U.S.C. § 343(g). The claim is that this exhausts the FDA's power with respect to a label when a definition and standard of identity have been prescribed and that, conversely, label regulation under § 403(j) exhausts the agency's power with respect to foods purporting to be o represented for special dietary uses. It is argued that the two subsections represent two contrasting and mutually exclusive regulatory philosophies, each appropriate only within its limited sphere: With respect to "foods with long histories of use," the approach was to hold manufacturers

to a "'time-honored' standard" by use of the standard of identity power and the accompanying limited authority of § 403(g); but with respect to the less familiar foods for special dietary use, "where there are no time honored recipes and where the knowledge of the importance of vitamins and minerals to health is changing rapidly," a requirement of full disclosure was thought better protection for the consumer.

This argument finds support neither in the language of the statute nor in its legislative history. In sharp contrast to § 403(i),[13] nothing in § 403(j) restricts its applicability to cases where no standard of identity has been prescribed. The fair reading of the statute is rather that, in the case of foods for special dietary uses for which standards of identity have been prescribed, Congress wished to authorize the FDA to require label disclosure not only of optional properties, as in the case of other foods with standards of identity, but of mandatory ones as well. Nothing in the legislative history is persuasive to the contrary. The statement in *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218, 230 (1943), that the purpose of Congress was "to require informative labeling only where no such standard [of identity] had been promulgated, where the food did not purport to comply with a standard,

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13 This provides that a food shall be deemed misbranded:

> (i) *If it is not subject to the provisions of subsection (g) of this section* unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: Provided, That, to the extent that compliance with the requirements of clause (2) of this subsection is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

21 U.S.C. § 343(i) (emphasis supplied).

or where the regulations permitted optional ingredients and required their mention on the label," *see also* 318 U.S. at 232, was made with a view only to the interrelationship of subsections 403(g) and (i), and has no bearing on subsection 403(j).

The evidence supporting the need for both a qualitative and a quantitative standard of identity was impressive. We set out below the more important findings of fact (omitting references):

> 3. The establishment of a standard of identity and quantitative limits for the nutrient ingredients in dietary supplements will reduce consumer confusion concerning choice of dietary supplements by insuring a basically rational formula for all products.
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> 7. The sale and use of vitamin/mineral preparations in the United States are extensive, running into hundreds of millions of dollars annually in wholesale bulk value, and involve three-fourths of American households. The majority of such preparations differ qualitatively and quantitatively from each other, presenting a bewildering variety to the consumer.
>
> 8. Many dietary supplements are nutritionally irrational, in that they provide quantitative levels and qualitative combinations of nutrients for which no human individual need could possibly exist, if the products are used only as dietary supplements. Lay persons are incapable of determining, by themselves, whether they have or are likely to develop vitamin or mineral deficiencies.
>
> 9. Although approximately 20 percent of the users of dietary supplements of vitamins and minerals actually use those articles to supplement or balance their diet, more than 40 percent of those persons admit

> they have no idea which vitamins or minerals, if any, are not sufficiently supplied by their diet.
>
> 10. Certain basic vitamins and/or minerals should be included in all articles offered as multivitamin and/or multimineral supplements. The remaining group of appropriate vitamins and/or minerals are considered to be scientifically optional for inclusion. The mandatory group of vitamins and/or minerals found in multivitamin and/or multimineral supplements should include all those listed in the table entit'ed "Recommended Daily Dietary Allowances, Revised 1968" in publication 1694 of the National Academy of Sciences.

38 F.R. 20734-35 (1973). And again:

> 22. The establishment of qualitative and quantitative limits on the composition of dietary supplements will reduce consumer confusion concerning choice of dietary supplements by ensuring a basically rational formula for all products.

Id. at 20735. Although some petitioners have pointed up record references in these findings of fact which the FDA is mis-citing or misreading, and could have pointed up many more, nevertheless the agency had ample evidence to conclude that a consumer seeking a dietary supplement of a given vitamin or mineral, whether singly or in combination with others, is faced with a dazzling array of recommended daily dosages and that a consumer seeking a multiple supplement is faced with an equally dazzling array of combinations; that neither consumer is given any basis for intelligent selection; and that it would "promote honesty and fair dealing in the interest of consumers," Conclusion of Law ¶ 1, 38 F.R. 20737 (1973), quoting § 401,

to promulgate the qualitative and quantitative standards of identity of new Part 80, *see* Conclusions of Law ¶¶ 2, 3, *id.* An FDA compliance officer submitted a chart, not purporting to be exhaustive, showing 59 multivitamin and/or multimineral products he had found on the market. The number of ingredients ranged from a low of 9 to a high of 57, with all kinds of intermediate variations. The dosage per tablet or capsule of vitamin C, for example, ranged from 30 to 500 mg., and the compliance officer referred to hundreds of instances of labels showing a daily dosage of a given mineral or vitamin in excess of the RDA. Offering a specially acute example of this, Dr. Herbert, an FDA witness, cited a particular B_{12} supplement sold as a general dietary supplement which had 25 times the strength even a strict vegetarian would need. There was evidence from which the agency was entitled to conclude that consumers are ill-equipped to choose from this galaxy of offerings[14]—as if the point would be in doubt in any event. And if expert testimony on the precise question of the usefulness of the standards of identity in overcoming all this was necessary, the FDA took the precaution of getting some—albeit of a conclusory nature.[15]

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14 While promotional abuses may not in themselves be sufficient to require resort to the standard of identity power, it is worth noting that manufacturers have frequently done their best to reduce still further the consumer's scant ability to select the product appropriate to his needs. An advertisement for Vital Foods, Inc., for example, featured Fero-B-Plex Vitamin B-Complex With Iron and boasted that "There is no other Vitamin B-Complex that can compare with FERO-B-PLEX for superior nutritional results. Once you use this famous formula, you'll never again be satisfied with ordinary B-Complex products." An advertisement for "Nutri-Time" announced "NEW! IN ONE SMALL TABLET . . . Never before have you been offered these vitamins and minerals plus other factors in these potencies;" 37 ingredients were shown and the potencies ranged up to 1500% of the adult MDR's. Further examples abound.

15 While there was expert disagreement as to the scientific meaningfulness of classifying ingredients as "mandatory" and "optional" rather than simply as "essential," the agency was entitled to choose between the conflicting views.

The FDA considers, with what seems to us, at least in general, *cf.* p. 5241 *infra*, entirely sufficient reason, that neither the new label requirements nor additions that might be made to these will suffice to eliminate consumer confusion. The subject matter is simply too recondite and the offering of products too diverse for a label alone to be "clear enough so that, in the words of the prophet Isaiah, 'wayfaring men, though fools, shall not err therein' . . . ," *General Motors Corp.* v. *FTC*, 114 F.2d 33, 36 (2 Cir. 1940) (A. N. Hand, *J.*), *cert. denied*, 312 U.S. 682 (1941). Thus, again passing to Part IV of this opinion special problems with respect to the propriety of using the U.S. RDA's to set maximum daily dosages, and passing to Part V an important and related procedural objection, we hold the agency was justified, as a matter of good sense, in concluding that the stated purposes of § 401 would be furthered by promulgating qualitative and quantitative standards of identity in this area so as to allow for some 30-odd products (each with limited variability of daily dosages) rather than the hundreds now on the shelves of food and drug stores.

There remain, however, the questions whether the standards promulgated are within the agency's general statutory power and, if so, whether they are "reasonable" within the meaning of § 401. Before considering these questions, it will be useful to review the authorities.

The Supreme Court has dealt with § 401 on only two occasions in the 36 years of the statute's history. The first was *Federal Security Administrator* v. *Quaker Oats Co.*, *supra*, 318 U.S. 218. Quaker Oats had been marketing a concededly wholesome and accurately labeled product as "Quaker Farina Wheat Cereal Enriched with Vitamin D" or "Quaker Farina Enriched by the Sunshine Vitamin." The Administrator promulgated a standard of identity

for farina which made no provision for the addition of any ingredient; he promulgated another standard for enriched farina which required the addition of prescribed minimum quantities of vitamin B_1, riboflavin, nicotinic acid and iron, ingredients of natural wheat lost in modern milling processes, and which allowed enrichment by vitamin D or certain minerals, *see* 129 F.2d at 78, only as optional additional ingredients. The Quaker Oats product thus could not be sold either as "farina" since it contained the additional ingredient vitamin D, or as "enriched farina" since it did not contain the prescribed enrichment. The Court sustained the regulations.

The decision could perhaps have been rested on the basis that Quaker Oats had no real intention of marketing its product as farina *simpliciter* or as something clearly *sui generis*, and that its joinder of the words "farina" and "enriched" was misleading; the Administrator, this argument would run, was entitled to encourage and safeguard a belief on the part of consumers that "enrichment" would replace all the elements removed from natural wheat by the milling process, of which vitamin D is not one. But Chief Justice Stone preferred to uphold directly the barring of the product from sale as *either* enriched farina *or* farina.[16] The Court began by mentioning that "[t]he composition of these enriched products [flours and farinas] varied widely," 318 U.S. at 225 & n. 5, although the cited variants were eight rather than the hundreds at issue here. It referred, in language entirely applicable here, to testimony by nutritionists that "such products, because of the variety and combination of added ingredients, are widely variable in nutritional value; and that consumers generally

16 On the question whether Quaker Oats might still market the cereal in some way clearly differentiating it from either farina or enriched farina—a question of little or no real commercial significance—*see* p. 5236 and note 20 *infra*.

lack knowledge of the relative value of such ingredients and combinations of them." *Id.* at 226. As here, there was expert testimony tending to support a conclusion of consumer confusion and recommending the adoption of the definitions and standards. *Id.* at 226, 228-29. Thus, after referring to the statutory criterion of promoting "honesty and fair dealing in the interest of consumers," Chief Justice Stone said that "[t]aking into account the evidence of public demand for vitamin-enriched foods, their increasing sale, their variable vitamin composition and dietary value, and the general lack of consumer knowledge of such values," there was sufficient evidence "to support the Administrator's judgment that, in the absence of appropriate standards of identity, consumer confusion would ensue." *Id.* at 228-29. In the most critical passage of the opinion, the Chief Justice summed up, *id.* at 230-31 (footnote omitted):

> The provisions for standards of identity thus reflect a recognition by Congress of the inability of consumers in some cases to determine, solely on the basis of informative labeling, the relative merits of a variety of products superficially resembling each other. We cannot say that such a standard of identity, designed to eliminate a source of confusion to purchasers—which otherwise would be likely to facilitate unfair dealing and make protection of the consumer difficult—will not "promote honesty and fair dealing" within the meaning of the statute.

Turning finally to the argument that "it is unreasonable to prohibit the addition to farina of vitamin D as an optional ingredient while permitting its addition as an optional ingredient to enriched farina," *id.* at 231, the Court said, *id.* at 232-33:

> We must reject at the outset the argument earnestly pressed upon us that the statute does not contemplate a regulation excluding a wholesome and beneficial ingredient from the definition and standard of identity of food. The statutory purpose to fix a definition of identity of an article of food sold under its common or usual name would be defeated if producers were free to add ingredients, however wholesome, which are not within the definition . . . .
>
> Since the definition of identity of a vitamin-treated food, marketed under its common or usual name, involves the inclusion of some vitamin ingredients and the exclusion of others, the Administrator necessarily has a large range of choice in determining what may be included and what excluded. It is not necessarily a valid objection to his choice that another could reasonably have been made. The judicial is not to be substituted for the legislative judgment. It is enough that the Administrator has acted within the statutory bounds of his authority, and that his choice among possible alternative standards adapted to the statutory end is one which a rational person could have made . . . .

Although some petitioners contend that *62 Cases of Jam* v. *United States*, *supra*, 340 U.S. 593, sounded a retreat from *Quaker Oats*, we do not consider it to be such.[17] The case turned on § 403(e) which says that a food shall be deemed misbranded:

> If it is an imitation of another food, unless its label bears, in type of uniform size and prominence,

17 Mr. Justice Frankfurter, the author of *62 Cases of Jam*, had concurred in *Quaker Oats*.

the word "imitation" and, immediately thereafter, the name of the food imitated.

21 U.S.C. § 343(c). The Court held that a product labeled as an imitation jam was not misbranded simply because it contained less fruit than would have been dictated by the standard of identity for a fruit jam. We need not determine whether this would permit a manufacturer to market a product containing less than the prescribed minimum limits for vitamins and/or minerals—or containing more than the maxima or a nonstandard combination—as an imitation; none of the manufacturer petitioners has expressed any desire to do this and none of the consumer petitioners has intimated any interest in having such products available.[18]

The cases in the courts of appeals certainly do not detract from *Quaker Oats*, as they hardly could, and may even go a bit beyond it in one particular hereinafter discussed, *see* note 20 *infra*. The leading ones are *Libby, McNeill & Libby* v. *United States*, 148 F.2d 71 (2 Cir. 1945), upholding the seizure as misbranded of a product, sold as "tomato catsup with preservative," which contained sodium benzoate in addition to the prescribed ingredients for catsup; *United States* v. *20 Cases . . . "Buitoni 20% Protein Spaghetti,"* 130 F. Supp. 715 (D. Del. 1954), *aff'd on the opinion below*, 228 F.2d 912 (3 Cir. 1956), upholding the seizure of spaghetti containing 20% protein as against a permitted maximum of 13%; and, finally, a case which did not seriously test the limits of the agency's statutory authority, *Corn Products Co.* v. *HEW*,

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18 Indeed, although at argument government counsel, apparently on the spur of the moment, mentioned the possibility of such marketing, his intention being to demonstrate that the regulations here at issue are not as restrictive as they might at first appear, the word "imitation" would be commercial death in an industry where naturalness is next to godliness.

427 F.2d 511 (3 Cir.), *cert denied*, 400 U.S. 957 (1970), upholding a regulation which required a 90% peanut content in peanut butter.

So far as concerns the statutory text, petitioners' main argument is that, in fixing a standard of identity for "dietary supplements" of vitamins and/or minerals, the FDA has gone beyond its authority since this is not a "common or usual name" of a particular food but rather an imposed functionally oriented denotation of a class of foods. The statute says, however, that a reasonable definition and standard of identity shall be prescribed for a food "under its common or usual name *so far as practicable*" (emphasis supplied); Congress thus seems to have envisioned the possible need to prescribe a reasonable definition and standard of identity for a food or a class of foods under something other than "its common or usual name." Moreover, our examination of the record discloses that, despite the enormous variations of content within the class of dietary supplements, vitamin and/or mineral preparations and multivitamin and/or mineral preparations are commonly sold under the shared rubric "dietary supplement." While this may initially have been due to a desire of the producers to make clear that they were operating under the label requirements of Part 125 rather than of § 502, 21 U.S.C. § 352, relating to drugs, nevertheless the name has become "common and usual" for the full range of such products. Indeed in light of this, given a product of the kind here at issue and giving the manufacturer credit for not harboring a therapeutic intent so that his product is not thereby classifiable as a drug, *see* Part III *infra*, the agency had every reason to conclude that such a product by its very existence "purports to be" what most people now know as a "dietary supplement." *Cf. Libby, McNeill & Libby* v. *United States, supra*, 148 F.2d at 72-73; *United States* v. *20 Cases . . . "Buitoni 20%*

Protein Spaghetti," 130 F. Supp. at 717-18; note 20 *infra.* The conclusion is in no way rebutted by a claim that "dietary supplement" describes a class of foods rather than a single food, since it is in the very nature of a standard of identity that it standardizes to a single formula (or here a selected group of formulae) what used to be a varied class of products. Any remaining objection must rather be to the purposes and consequences of delineating the class in a particular way, which brings us to petitioners' second line of attack.

This is based on legislative history. As petitioners correctly point out, Congress' dominant concern in enacting §§ 401 and 403(g) was to combat "economic adulteration." One of the Senate Reports, S. Rep. No. 361, 74th Cong. 1st Sess. (1935), in Dunn, Federal Food, Drug, and Cosmetic Act 237, 245-46 (1938) [hereinafter cited as Dunn], noted, for example, that "[b]utter [before enactment of the earlier Butter Standards Act] was found on the market with a fat content varying from about 66 to 85 percent or more. Some manufacturers deliberately worked water into their product, thus obtaining butter prices for water and at the same time curtailing the market for the dairy-farmers' butterfat . . . . Conditions similar to those which prevailed with respect to butter exist today with many other food commodities and can be corrected only by the action here authorized." A later House Report on the same bill, H.R. Rep. No. 2139, 75th Cong. 3d Sess. (1938), in Dunn at 815, 819, said, "One great weakness in the present food and drugs law is the absence of authoritative definitions and standards of identity except in the case of butter and some canned foods. The Government repeatedly has had difficulty in holding such articles as commercial jams and preserves and many other foods to the time-honored standards employed by housewives and

reputable manufacturers. The housewife makes preserves by using equal parts of fruit and sugar. The fruit is the expensive ingredient, and there has been a tendency on the part of some manufacturers to use less and less fruit and more and more sugar. . . . By authorizing the establishment of definitions and standards of identity this bill meets the demands of legitimate industry and will effectively prevent the chiseling operations of the small minority of manufacturers . . . ." Petitioners also place great reliance on a passage where the Senate Report went on to say that § 401 sought to prevent products with nonstandard—and generally cheapened—recipes from being marketed under standard-product names, but was not intended to *bar* the marketing as a food of any recipe not proved harmful: "It should be noted that the operation of this provision will in no way interfere with the marketing of any food which is wholesome but which does not meet the definition and standard, or for which no definition and standard has been provided; but if an article is sold under a name for which a definition and standard has been provided, it must conform to the regulation." S. Rep. No. 361, *supra,* in Dunn at 246. The same thought appears in the House Report: "Under this a single reasonable standard of quality can be prescribed for any food and if the product falls below this standard it must be labeled as substandard [but can still be marketed]." H.R. Rep. No. 2139, *supra,* in Dunn at 819.

Again we find several answers. The most obvious is that Congress was not focusing on any such problem as is presented here. Even if Congress' paramount concern in enacting § 401 was with cases of economic adulteration, any limitation of the section's scope to such instances would run afoul of the portion of *Quaker Oats* which sustained the banning of the vitamin D enriched product

from sale even as farina.[19] A rule that a standard of identity may never totally ban the sale of a product, provided only that it be labeled as substandard, may also have gone by the board with *Quaker Oats;* in *62 Cases of Jam, supra*, 340 U.S. at 598, Mr. Justice Frankfurter seems to have read that case as holding that the product "could not be sold" in any form.[20] Moreover, even if a

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19 It might well also run counter to the *Buitoni* case cited earlier in the text—although it is not altogether clear that that court would have considered the issue to be before it, *see* 130 F. Supp. at 717, 718. There does not appear to have been evidence that the additional 7% of protein supplied by gum gluten was cheaper than an equivalent content of other items; for all that appears, it was just different.

Similar considerations, and in particular the very facts of the *Quaker Oats* case, suffice to refute the contention of some petitioners that, at least as to beneficial as distinguished from dilutant ingredients, the agency has authority only to prescribe minimum content levels and not maxima. *See* 318 U.S. at 232 ("The statutory purpose . . . would be defeated if producers were free to add ingredients, however wholesome, which are not within the definition.").

20 Shortly thereafter, Justice Frankfurter intimated a slight retreat from this reading, suggesting that the possibility may have remained of Quaker Oats' marketing its product as an "imitation," 340 U.S. at 599; as previously noted, however, this refinement is of no consequence to the present case.

The *Libby* and *Buitoni* cases, *supra*, may suggest even more strongly than *Quaker Oats* the legitimacy—apart from the special exception for "imitations"—of barring a wholesome product altogether from sale as a food. Although both were seizure actions, and therefore could not raise such questions in quite the same direct and general way as does a petition for review, *see* 130 F. Supp. at 717, 718; note 19 *supra*, the language of the two opinions makes it difficult to imagine that the courts deciding these cases would have allowed the two products there at issue to be marketed under any name and in any fashion that would have exempted them from the relevant standards of identity. Libby's only interest was in marketing "a product that looks, tastes, and smells like catsup, which caters to the market for catsup, which dealers bought, sold, ordered, and invoiced as catsup . . . ." 148 F.2d at 73. Similarly, no changes in merchandising technique would have altered the fact that Buitoni's product "looks like spaghetti in form, length and diameter. It is similar in color to other brands of spaghetti. Its retail packages are the same general size, shape, and physical appearance as those used by other spaghetti manufacturers. It is manufactured from the same raw material as spaghetti." 130 F. Supp.

prohibition of total bans might make sense in some situations, the present case is precisely the type of case where, under the logic of *Quaker Oats*, it would not apply. For while that decision establishes beyond question that Congress wanted § 401 to be read to cover some nonadulteration cases such as that here in issue, so much of the legislative history earlier quoted as suggests a rule against total bans by use of the § 401 power *was* directed narrowly to adulteration and similar problems. The remarks in the Senate and House Reports to the effect that there will be no total bans thus say nothing more than that *cheapened* products may still be marketed, provided they are properly marked. But here, as in the "farina" branch of *Quaker Oats*, not cheapening but the *variety* of available products is the problem; to allow the total array to continue to be marketed under some other name—for example, by avoiding use of the term "dietary supplement" or any equivalent—would, in such a special situation, render useless the § 401 power which we believe Congress intended to have available to the agency in a variety of unanticipated circumstances such as that now presented. The remarks in the legislative history regarding total bans simply do not speak therefore to cases such as that before us.[21]

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at 717-18 (footnotes omitted). Although in each case the product name included the standard word "catsup" or "spaghetti," we do not read the opinions as resting at all heavily on that ground. The fact is that, as a practical matter and the "imitation" exception aside, the Libby and Buitoni products were effectively banned from the market by those two decisions under § 401.

21 It is to be noted in this regard that with one, or possibly two, sets of exceptions discussed in the next section of this opinion, the FDA does not seek altogether to bar any individual nutrients (as distinguished from particular dosages thereof) from separate sale. Therefore, while we shall find that in those two particular sets of instances any such total ban is unreasonable, it is not necessary for us to decide whether total bans on sale as foods of nontoxic individual nutrients would in all cases be beyond the agency's statutory authority.

The petitioners also argue that the standard of identity is not "reasonable" as required by the language of § 401 or, for similar reasons, is "arbitrary" or "capricious" within the terms of the Administrative Procedure Act, 5 U.S.C. § 706. Much of their fire here is directed at the upper limits; they say essentially that there can be nothing wrong in giving a consumer more of a good thing when there is no claim of toxic effect. But the argument ignores that the purpose of a standard of identity is not simply to protect against unwholesomeness or adulteration but to "promote honesty and fair dealing in the interest of consumers." Advertising a potency in excess of the upper limits is bound to make consumers think they are getting a superior product when, in the FDA's view, they are not; furthermore, particularly in light of experience to date with the minimum daily requirements and passing still the appropriateness of the use of the RDA's for this purpose, the agency was far from irrational in concluding that, at least in general, *see* p. 5240 *infra*, the problem would not be fully obviated by prescribing a label statement that the potencies exceeded the RDA's by particular amounts. Petitioners argue also that it is unreasonable to prevent a purchaser from obtaining any combination he may desire by restricting him to the FDA's list of all vitamins and minerals, all vitamins, all minerals, or all vitamins and iron. So far as concerns the sophisticated purchaser this may well be so. But the FDA was entitled to give thought to the ordinary consumer, who may be harmed, for example, by purchasing a less inclusive combination while believing that he is getting everything he needs. Again it was far from irrational, at least as a general matter, for the agency to conclude that no label statement could fully meet this problem. Striking a proper balance among the interests of sophisticated and unsophisticated consumers is for the agency, not for a reviewing court.

Some petitioners urge that if a purchaser of a combination wishes more than the upper limit of some particular vitamin or mineral, he will be condemned to more than he wants of many others. But this ignores that such a purchaser, who by very statement is one of some sophistication, can avoid the problem by taking both the combination and the single vitamin.[22] To be sure, even this may give him a dosage somewhat exceeding precisely what he desires,[23] but again the FDA was entitled to weigh such disadvantages against what it considered the larger good.

Concededly, in each of the situations we have just discussed, the consumer who is disappointed by not being able to obtain precisely the dosage or combination he seeks in the standardized products is likely to find his costs somewhat increased if he sets about achieving the same result by purchasing larger numbers of a particular type of pill, or even by purchasing a little of this and a little of that. Such an increase in effective price, and the likely consequential decrease in unit sales by the manufacturers, is, however, a paradigmatic example of the kind of consideration the agency may find outweighed by public needs.

Finally, the fact that the agency chose not to extend the standard of identity requirements to the nonessential

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22 If the agency determines that the procedure of taking multiple dosages of the standardized combination pills will appeal or is appealing to some unsophisticated purchasers as a means of getting more than the upper limit of some particular nutrient or nutrients, it may impose additional warning requirements concerning the wastage involved and, as to the fat-soluble vitamins, possible toxicity. The point is, however, that the agency has full discretion to determine that *this* is a problem adequately met by a fully informative label (if it requires action at all), and that the problem of unsophisticated consumers confronting a dazzling array of combinations and dosages, on the other hand, is a more severe one requiring a more drastic solution.

23 If dissatisfaction on this score is at all widespread, we can count on the free market to take full advantage of the § 80.1(b)(5) exemption and provide individual nutrients in finely gradated dosages up to 50% of the adult U.S. RDA.

nutrients listed in § 125.2(b)(5), *see* n. 68 *infra*, when individually marketed in the limited manner permitted by that subsection, or, § 80.1(b)(5), *supra*, to vitamins and minerals in daily dosages less than 50% of the adult U.S. RDA not represented as dietary supplements and labeled in accordance with 21 C.F.R. § 1.17, *cf.* 38 F.R. 6951, 6959-61 (1973), in no way renders the regulation unreasonable or arbitrary within its selected sphere. The Agency might well have believed that the preclusion from marketing the exempted products as dietary supplements, together with the present and possible future provisions of § 1.17 specifically invoked by § 80.1(b)(5), would prevent these products from causing the same problems of consumer confusion presented by those products to which the Part 80 standards do apply; it might at the same time have believed that no such limitations on marketing technique could obviate the problem of confusion with respect, for example, to products which could honestly be said to contain very large dosages of essential nutrients, or even that it was precisely because of the drastic simplification of product displays sought by Part 80 as a whole that the limited § 125.2(b)(5) and § 80.1(b)(5) exemptions would be tolerable. In any event, it was for the agency to decide how far to reach with this particular remedial effort.[24]

Despite all this we are concerned that the all-or-nothing attitude adopted by both sides in this long and bitter

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24 Even more clearly, there is nothing arbitrary or unreasonable, as some petitioners urge, in the agency's exempting raw agricultural commodities and fortified substitutes therefor which are not represented as dietary supplements. Even apart from the question of statutory authority in this regard, compare Part VII *infra*, the fact that such products may offer enormous dosages of some nutrients does not compel a conclusion that they contribute to the same kind of consumer confusion that motivated promulgation of the Part 80 standards of identity —particularly when modes of use with regard to them are significantly regulated by longstanding dietary habits and by the sheer limitations of appetite.

controversy may have led the FDA into proscribing some combinations whose sale should be permitted under the standards of § 401 and into prescribing some maxima where a good case can be made for allowing an excess. *Cf. Staley Mfg. Co.* v. *Secretary of Agriculture*, 120 F.2d 258, 260-61 (7 Cir. 1941). Without intending either to prejudge or to be exclusive, vitamin B complex may represent an example of the former and vitamin C, sold as a single vitamin, of the latter. It is hard for us to see how a bottle plainly and simply labeled vitamin B complex contributes sufficient confusion that the goal of honesty and fair dealing should require a consumer who desires the various types of vitamin B to purchase several bottles rather than one; similarly, and in light of the testimony as to particularly wide variations in philosophy concerning the optimal intake of vitamin C, we are not convinced as things stand that a consumer who believes a 500 milligram pill of vitamin C, a quantity now frequently sold, will maintain his optimal body stores should be required to purchase five or six pills of ninety mg. each, at greatly enhanced cost.

Although the FDA has evinced some small concern for the need for such differentiation—and it was not particularly encouraged in this regard by petitioners—we do not believe that it has gone far enough. In regard to the maxima, the agency did attempt, largely on the testimony of Dr. Sebrell, *see* p. 5269 *infra*. to update in scientific terms what was then the latest edition of the RDA's with respect to particular nutrients, and there was also other sporadic testimony pro and con with regard to the upper limits for particular ingredients. But the agency made no effort to draw the parties into a comprehensive study of the possibility of raising some upper limits, and particularly of raising them even if scientific considerations were somewhat against it simply because such moves in selected cases

might meet real and not altogether irrational market demands without contributing appreciably to consumer confusion, nor any particular effort to deal in its findings with such testimony on particular upper limits as did happen to arise. Neither has provision been made for ready flexibility along these lines in the future: The upper limits are to be responsive to RDA changes based on new nutritional knowledge, §§ 80.1(f)(2), 125.1(b)(1); but there is no provision that they be responsive, for example, to a demonstration that (1) vast multitudes of consumers and significant numbers of nutritionists reject, *e.g.*, the FDA's view that 500 mg. per day of vitamin C is without nutritional value, and that (2) the availability of such dosages as foods, clearly marked and flagged with necessary warnings, may not confuse anyone. On the present record it seems to us distinctly possible that such a demonstration could be made.[25]

With respect to combinations of less than all essential ingredients, the agency itself apparently recognized that it had given at most sporadic consideration to the possibility that some exceptions might be in order. Hence greater and procedurally more particularized future flexibility is presumably provided by § 80.1(b)(4), which we set out in the margin.[26] It has long been settled that an

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25 The exceptions of the parties to the tentative regulations, with which no one seems to have provided us, do not appear to have tested the agency's flexibility in this regard. Apart from a special attack on the maximum (and minimum) figure for folic acid, 38 F.R. 20732, ¶ 17 (1973), the only discussion we find in the preamble to the final regulation of the possibility of needing to increase the maxima appears in paragraph 14, *id.* This paragraph in no way suggests that the exceptions of particular parties urged increases in particular maxima, nor reflects agency consideration of such possibilities.

26 (4) Addition to or amendment of the list of permissible combinations of vitamins and/or minerals contained in paragraph (b)(1) of this section may be proposed by the Commissioner of Food and Drugs, on his own initiative, or upon petition by an interested

agency may adopt a rule shown to be appropriate for the generality of instances and leave the correction of injustices to applications by those concerned, *see The New England Divisions Case,* 261 U.S. 184, 204 (1923), and we would, of course, expect the FDA to apply this subsection in good faith and with dispatch. However, while paragraph 3 of the preamble to the final regulation, 38 F.R. 20731 (1973), implicitly suggests that some petitions seeking such particularized amendments may have been received with the exceptions to the proposed regulations, the agency has not provided us with the relevant exceptions, nor with a listing of those (if any) which included § 80.1(b)(4) petitions, nor does the preamble contain any real assurance that the agency separately considered any such particularized applications that did come in. Compare 38 F.R. 20710, ¶ 10 (1973). Moreover, even apart from the important point that the escape clause relates only to combinations and not to the maxima, it is not sufficiently clear to us on the wording of § 80.1(b)(4), and certainly not on the cryptic wording of paragraph 3 of the preamble, that the agency intends to evaluate § 80.1(b)(4) petitions in light of a balancing of freedoms infringed against the increased dangers of consumer confusion which would be triggered by allowance of each additional product—as we believe the reasonableness requirement of § 401

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person in accordance with the procedures set forth in Part 2 of this chapter. Any such petition shall be submitted in the form set forth in § 2.65 of this chapter, and shall include scientific data of a human nutritional and/or technological nature to support such addition or amendment as being consistent with the definition and purpose of dietary supplements as described by this section. The Commissioner, upon request, may extend the effective date of this section with respect to any particular product or class of products pending consideration and any administrative or court proceedings relating to any such petition, and may set a new effective date upon completion of the matter.

38 F.R. 20738 (1973).

requires it to do, in a manner set forth in greater detail below. Rather § 80.1(b)(4) may suggest an absolute insistence on new scientific data similar to what would be required to modify the RDA's. Finally, even if the FDA would apply the appropriate criteria in this area should § 80.1(b)(4) petitions now begin to flow, it would be commercially disruptive for a product to have to be withdrawn from sale in January 1975 only to be returned to the market in July.

In light of all these considerations, we direct that § 80.1(b)(4) be modified to permit upward revisions in the maximum for particular vitamins or minerals and that the criteria be broadened to conform to the standards of § 401. We also believe the agency should receive and deal explicitly with applications for increases in particular upper limits and applications under the present § 80.1(b)(4) before the regulations become effective. To this end we think it necessary to stay the regulations in their entirety, and not just those parts establishing the standard of identity, since, for example, a stay affecting only the standard of identity would force a B-complex manufacturer to change over to the new label imposed by the new regulations while knowing full well that if his § 80.1(b)(4) application was denied his line would be off the shelves when the limited stay expired. We therefore order a stay of the regulations until six months after our judgment becomes final or June 30, 1975, whichever is later, a period which should be sufficient for the FDA to pass on at least the most meritorious applications both as to dosages and as to additional combinations.[27]

The FDA should establish dates for the filing of such applications and, if these should prove to be numerous, procedures to screen out the most meritorious for early

27 Of course, the FDA may extend the stay, or a party who has filed an application may ask us to do so.

hearing and decision. In determining whether it is "reasonable" to deny a particular application, the primary consideration must of course be the degree of increase in potential consumer confusion. Since the sheer variety of products is a central problem here, the applications will in a real sense be in competition with one another, and we do not expect a very large number to be granted. It would be reasonable in resolving this competition to favor products which, because of widespread prior publicity or even just because of simplicity of terminology, are unlikely to confuse many consumers when properly labeled. Indeed, we specifically direct that the FDA consider any such applications as to vitamin C in larger dosages and vitamin B complex supplements. Moreover, against any danger of slight increases in confusion should be weighed such factors as the following: (1) how large is the consumer demand for the product at present, and how widespread any expert belief that it is not an irrational product for a significant number of consumers;[28] (2) how effectively could any potential confusion with respect to the particular product be reduced or eliminated by requiring on the label (A) with respect to a high dosage product, a legend to the effect that the FDA has determined this product contains quantities of such-and-such nutrient not normally essential to human health, or (B) with respect to a combination, a legend to the effect that the FDA has determined this product does not contain all the nutrients essential to human health;[29] and (3) in the case of applications to exceed the upper limits, how dependable, if this can be determined, is the particular NAS RDA on which the upper limit is based relative to other RDA's, *cf.* Part IV *infra*. We wish to make clear that, while it

28 *See also* note 42 *infra*.

29 Obviously, the manufacturer of a product in this latter category could be prohibited from using the words "multivitamin" and/or "multimineral."

would defeat the purposes of Part 80 for a very large number of such applications to be granted, either with respect to dosage limitations or with respect to combinations of less than all essential ingredients, we expect each application to receive the most serious consideration on its merits relative to the criteria just outlined. At the same time it should be obvious to the petitioners that we are broadly sustaining the regulations and that any attempt to convert the procedures we are here directing into something like a nearly complete reopening of the proceeding will be counter-productive. Indeed, if an avalanche of petitions for exceptions should occur, the agency would be justified in denying all applications (except those as to increased dosages of vitamin C and vitamin B complex supplements), without prejudice to subsequent renewal, on this ground alone. What we are doing is to provide the industry with another chance for individualized consideration of the most meritorious cases for exceptions. An exercise of responsibility on the part of the industry will be necessary if this is to confer the benefits we intend.

III. *The Banning of Certain Essential Nutrients and the Classification As a Drug of Any Product Containing Quantities in Excess of the Upper Limits*

Before examining the validity of the U.S. RDA's for the purposes for which the FDA has used them, we shall consider two other matters which, although more comfortably seen in our view as elements of the standard of identity scheme, appear in Part 125 relating to Label Statements.

Section 125.1(c) recognizes that, in addition to the 12 vitamins and 7 minerals approved as mandatory or optional ingredients, *cf.* table at p. 5212 *supra*, two other vitamins and six other minerals are essential to human nutrition. Nevertheless, because no U.S. RDA's have yet been established for them, these are banned "for addition to

general purpose foods or dietary supplements of vitamins and minerals," although they "may be added to such other foods for special dietary use as infant formulas, and foods represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions." If this language left open any possibility that these vitamins and minerals could be separately sold as foods, this would be foreclosed by §§ 80.1(b)(1) and (2), and 80.1(f)(1), which effectively ban the sale as dietary supplements of any vitamins or minerals not on the approved list.

We see no sufficient basis for such drastic treatment. At argument, government counsel sought to defend it both as a labeling requirement under § 403(j) or (a), and as a § 401 standard of identity. The regulation and the appurtenant findings of fact, however, contain no suggestion of implicit misrepresentation with respect to these nutrients comparable to the asserted basis of § 125.2(b)(5), discussed at pp. 5282-5283 *infra*, so as to justify § 125.1(c) under the labeling sections; and indeed, even where such a basis was asserted in § 125.2(b)(5), it evidently was not thought sufficient to justify a ban on separate sale. Thus, the only satisfactory view of § 125.1(c) is as part of the standard of identity scheme. As such, we hold the subsection is not "reasonable" within the terms of § 401. Assuming *arguendo* that bans on separate sale of nontoxic individual nutrients may at times be within the agency's statutory authority, *see* note 21 *supra*, the agency has articulated no basis for invoking such an extreme remedy here—particularly when it is not invoked as to the § 125.2(b)(5) elements, which the agency considers of far lower, indeed of negligible, nutritional rank. Moreover, even if § 125.1(c) were viewed exclusively as a ban on certain *combinations*, like § 125.2(b)(5), the evidence cited in support of the relevant finding of fact, ¶ 3 at 38 F.R.

20713 (1973), would not suffice to make the subsection reasonable. The relevant cited evidence concentrates almost exclusively on the lack of need for supplementation of the § 125.2(b)(5) elements; indeed, the cited evidence would support § 125.1(c) with regard to the vitamin choline at most—although petitioners in number 73-2175 point to one piece of additional testimony which might conceivably have supported it with regard to potassium and sodium as well. Finally, the failure of the FDA, after twelve years of proceedings, to fix U.S. RDA's for the vitamins and minerals listed in § 125.1(c) cannot in itself render the provision "reasonable."

Perhaps in the year that has elapsed since the regulations were promulgated, the FDA has now arrived at these figures and the list of optional ingredients with U.S. RDA's established can be readily expanded on remand. But in the meantime we shall enjoin enforcement of so much of the regulations as prohibits the inclusion of the vitamins and minerals listed in § 125.1(c) in general purpose foods,[30] or as optional ingredients in dietary supplements, including dietary supplements for separate sale under § 80.1(b)(2). We leave it to the agency on remand to integrate these nutrients into § 80.1(b)(1)(v), by determining whether addition of one of them shall require addition of all, or shall require addition of the other § 80.1(b)(1)(v) nutrients, and so forth.[31]

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30 Our holding, of course, has no bearing on standards of identity separately promulgated for individual general purpose foods.

31 This order extends also to any nutrients recognized as essential in human nutrition but not mentioned *anywhere* in the regulations—neither in the list of mandatory or optional nutrients, nor in § 125.1(c) (and of course not in § 125.2(b)(5), *see* p. 5282 *infra*). Counsel in number 73-2175, both in his briefs and at argument, has said that many such ingredients, such as cobalt and celenium, are implicitly banned from all sale as foods just as the list in § 125.1(c) is explicitly so banned. Government counsel began by denying at argument that this was the impact of the regulations even with respect to the § 125.1(c) list; when in the end he conceded that this was the import of § 125.1(c),

Petitioners also object, both as a matter of statutory authority and as a question of substantial evidence,[32] to

he did not make clear whether he also conceded that a number of unmentioned, presumably essential (*but see* findings of fact ¶¶ 11, 12, at 38 F.R. 20713 (1973, discussed immediately *infra*) nutrients are banned as well. Any such ban, if the affected nutrients were in fact essential, would have even less basis than § 125.1(c) itself, since there is *no* indication that the agency has given the unmentioned nutrients any separate thought, *but cf.* 38 F.R. 20710, ¶ 10 (1973), and since with respect to them there would not even be provision for the infant-formula and medical-supervision exceptions incorporated in § 125.1(c); indeed, even if the affected elements were not essential, we would have difficulty finding such a ban "reasonable" under § 401 in light of the unexplained contrast that would be presented to the treatment of the § 125.2(b)(5) elements. With the agency evidently not having entertained these considerations, and indeed with its counsel uncertain as to whether it has banned the unmentioned substances at all, we see no point in our pursuing the matter further at this time; we do not propose, for example, to review the record as it bears on the essentiality of all the unmentioned substances, and thus to determine whether the ostensibly comprehensive listing of essential nutrients in paragraphs 11 and 12, 38 F.R. 20713 (1973), is supported by substantial evidence, since it is not clear what the impact of any such determination on our part would be. Rather we order the agency, evidently for the first time in any comprehensive way, compare ¶ 10, 38 F.R. 20710 (1973), to direct its attention specifically to the unmentioned ingredients. It should first determine, based on the evidence in the record or additional evidence on remand and bearing in mind that §§ 80.1(b)(1), (2) and 80.1(f)(1) appear to ban any ingredients not specifically listed even from individual sales, whether it has omitted any essential nutrients. If so, these must be integrated, as we have already ordered with respect to the § 125.1(c) nutrients, into the list of optional ingredients and into § 80.1(b)(1)(v), pending the establishment of U.S. RDA's for them. Beyond this, the agency should articulate its intentions with respect to those unmentioned elements which it finds not to be essential. If it means to handle all of them under the "such as" language of § 125.2(b)(5), then it should expand the list of examples in that subsection or in some other way more clearly delineate its scope. If, on the other hand, the agency does mean to ban some unmentioned, nonessential ingredients even from individual sale, then it must articulate the basis of distinction of such substances from those now listed in § 125.2(b)(5). Judicial review of the handling of the unmentioned substances cannot even begin until the FDA has clarified matters at least to the extent just outlined. We expect the agency to complete this process before expiration of the stay granted in Part II *supra*.

32 Some petitioners direct a procedural attack as well, primarily concerning lack of notice, at § 125.1(h). In view of our holding that the

§ 125.1(h), providing, with certain exceptions intended to conform to the standard of identity exemptions in § 80.1(e), *supra*, that preparations containing more than the upper limits of the U.S. RDA per serving are drugs. This would implicate the many provisions of subchapter V of the Food, Drug and Cosmetic Act, including the more elaborate label requirements of § 502, 21 U.S.C. § 352, and, potentially, the burdensome provisions of § 505, 21 U.S.C. § 355, for approval of "new drugs"; would involve petitioners in an elaborate investigation now being conducted by the FDA into the composition, labeling and sale of over-the-counter drugs, including "[v]itamin-mineral products," 21 C.F.R. § 130.301(b)(8), with the possible result that their products could be sold only on prescription or under other limiting conditions, *id.* § 130.301(a)(5)(i); and might, we were informed at argument by counsel in numbers 73-2826 and -2834, result in various restrictions on sale in some states which automatically impose limitations on any product deemed a "drug" under federal law. In addition to defending on the merits,[33] the FDA says that this

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provision is substantively invalid, we need not consider this procedural argument—which we find of questionable merit in any event.

33 The FDA claims *inter alia* that the issue of statutory authority, *cf.* note 35 *infra*, has already been settled in its favor by the decisions, cited in Part I, *supra*, upholding other regulations, 21 C.F.R. §§ 3.94 and 3.95, requiring that preparations of vitamins A and D in dosages exceeding 10,000 and 400 international units, respectively, shall be restricted to sale as prescription drugs. But the dominant consideration in both those cases was the determination that the FDA had properly provided by rule that these preparations could be dispensed only on prescription by a physician under § 503(b)(1)(B), authorizing this in the case of a drug intended for use by man which

> because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug.

21 U.S.C. § 353(b)(1)(B). The decision that vitamins A and D in dosages above a given level were "drugs" at all was reached in the first opinion with a degree of ease obviously dictated by Judge Frankel's

provision was inserted *ex gratia,* since, without it, preparations exceeding the upper limits could not be sold at all. Whatever the purpose, petitioners attack the provision and are entitled to our judgment about it.

Section 201(g)(1) of the Act says:

> The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories.

21 U.S.C. § 321(g)(1). Although the findings on which the FDA apparently sought to rest § 125.1(g) were evidently based on subdivision (B) of § 201(g)(1), *see* 38 F.R. 20170, ¶ 12 (1973); *cf. id.* at 20715, ¶ 44; *id.* at 20735, ¶ 11, government counsel now suggest that they could properly have been based on subdivision (B), since all the vitamins and presumably all the minerals with which we are here concerned are recognized in the official United States Pharmacopoeia or the official National Formulary. If this argument be seriously advanced, a sufficient answer is the statement in *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962), that "[t]he courts may not accept

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view that they had properly been placed in the even more restrictive prescription category, and was reached in the second opinion without explicit treatment.

appellate counsel's *post hoc* rationalizations for agency action." Moreover, the argument would prove too much, for it would lead to the conclusion that all vitamin and mineral preparations even within the limits are drugs—a position which would run counter to the regulations.

The FDA's decision to handle as drugs all vitamin and mineral products in excess of the upper limits of the U.S. RDA's rested essentially on the thought expressed in paragraph 12 of the preamble to Part 125, 38 F.R. 20710 (1973): "The hearing record discloses no known food or nutrition use of nutrients at such high levels, and no such uses were shown in the exceptions." We believe that this mischaracterizes the record. As will emerge more fully in the next section of the opinion, dealing with the RDA's as a basis for the upper limits in the standards of identity, a significant number of persons have indisputable nutritional need for potencies exceeding the upper limits; in particular, and by no means exclusively, this includes the large number of women taking oral contraceptives.[34] In light of this, it cannot be said even as an objective matter that a given bottle of pills, each containing more than the upper limit of one or more nutrients, is not being used for nutritional purposes.

A fortiori it follows that the vendor of such a product can in good faith intend it for nontherapeutic use. Section 201(g)(1)(B) makes the vendor's intent the crucial element in the definition of "drug" here at issue, *see also* S. Rep. No. 361, *supra,* in Dunn at 240, and the cases consistently have read that language for its plain meaning.

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34 It is to be noted also, although this is of course not dispositive, that many common foods contain potencies per serving considerably above the upper limits. We are told, for example, that six ounces of fried beef liver contains 18 times the upper limit of vitamin A and that a glass of orange juice contains 140% the upper limit of vitamin C.

While we agree that a factfinder should be free to pierce all a manufacturer's subjective claims of intent and even his misleadingly "nutritional" labels to find actual therapeutic intent on the basis of objective evidence in a proper case, such objective evidence would need to consist of something more than demonstrated uselessness as a food for most people. We therefore hold that § 125.1(h) is invalid.[35]

Our invalidation of this subsection in no way prevents high-dosage products properly labeled from being marketed as over-the-counter drugs. But under our ruling § 125.1(h) will cease to have any independent restrictive force.

IV. *The U.S. RDA's and the Prescription of Upper Limits*

As has already appeared, the U.S. RDA's serve two different purposes in the FDA's regulatory scheme. One is the requirement, § 125.3(a), *see* note 4 *supra*, that "the label shall bear a statement of the percentage of the U.S. RDA of such vitamins and minerals, as set forth in § 125.1(b), supplied by such food when consumed in a specified quantity during a period of 1 day." The other consists of the substantive provision, § 80.1(c)(1), that "dietary supplements described in this section shall contain in the specified daily quantity no less than the lower limit nor more than the upper limit of any nutrient specified in paragraph (f) of this section for the group(s) for which the supplement is offered."

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35 While we thus reach this holding as a question of insufficient evidence, we must agree with petitioners that an administrative interpretation in such direct conflict with a legislative definition might also be invalidated on the ground of exceeding the agency's statutory authority.

There is little controversy over the label requirement.[36] Counsel for petitioners in Nos. 73-2746 and -2747 say expressly in their brief, p. 30 n. 33, "no one contests FDA's power to require such a [label] statement pursuant to Section 403(j)." And the reply brief of counsel in No. 73-2824, which, as we shall see, leads the attack on the RDA's in other contexts, states at pp. 2 and 12:

> Petitioner, Federation of Homemakers, supports and commends the agency for the development of a [sic] informational device which, if properly regulated and clearly explained to consumers, can be a major tool in eliminating much of the confusion and misunderstanding which pervades the vitamin market. . . . It is the position of Petitioner, Federation of Homemakers, that when properly used as an information tool as indicated in the NAS comment on the U.S. RDA the FDA has made a useful contribution to informing consumers and helping to provide clarifying information in the marketplace.

Similarly, as earlier mentioned, *see* note 10 *supra,* there is, and probably could be, no serious and separate objection, on an evidentiary basis or otherwise, to so much of § 80.1(c)(1) as proscribes the sale of a dietary supplement containing less than the lower limits of the U.S. RDA's.

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36 Petitioner in number 73-2748 does attack the reasonableness of imposing such a requirement with respect to products within the upper limits sold as foods while not at the same time imposing it with respect to higher dosage products sold as over-the-counter drugs. In context, however, we understand this argument to be intended not as an assault on § 125.3(a), but rather as part of the more general reasonableness attack, *see* pp. 5237-5240 *supra,* on the upper limits and on the standards of identity as a whole. In any event, it was perfectly reasonable for the agency to rely on the drug labeling provisions and the future course of the pending over-the-counter drug proceedings, *see* Part III *supra,* to handle the informing function with respect to high-dosage products which it chose not to reach with § 125.3(a).

In contrast there are violent objections to the use of the RDA's to prescribe upper limits.

As indicated by our discussion in Part II, *supra,* any attempt to prescribe an effective standard of identity had to deal in quantitative as well as in qualitative terms. The bewildering array of products confronting the consumer varied in terms of potency as much as in terms of specific nutrients contained. Although petitioners loudly criticize the U.S. RDA's, they suggest nothing to take their place in a standard of identity; rather, as suggested most pointedly by petitioners' reply brief in numbers 73-2746, 73-2747, and 73-2748, they would relegate the whole matter to a label which would say, at most, something like this: "The quantity of vitamin .... contained in this product is five times what the FDA considers necessary for proper nutrition." Yet, in light of experience with what amounted at least implicitly to a similar statement concerning the MDR's, the FDA might well have entertained doubt that, at least in general, *cf.* p. 5240 *supra,* such a warning would turn purchasers off rather than turn them on. While it was for the FDA to justify the regulations, not for the petitioners to show the agency what to do, we must be aware that invalidation of the upper limits would seriously impair, if not destroy, the value of the standards of identity.

Perhaps the central evidentiary attack on the maxima, which are generally 150% of the U.S. RDA's,[37] is that the FDA misapprehended the purpose of the National Academy

37 There are occasional exceptions to this ratio with regard to children under 4 and with regard to the category of older children and adults, and the general ratio does not apply at all with respect to the category of pregnant or lactating women.

Since for most people with balanced diets, ordinary foods will supply all necessary vitamins and minerals (except perhaps sufficient iron, *see* p. 5279 *infra*) without need of supplementation, supplementation by the maxima will provide them with 250% of what is deemed necessary.

of Sciences in promulgating the NAS RDA's on which the U.S. RDA's are based. This argument is most effectively presented in the reply brief in No. 73-2824, where counsel have reprinted a section entitled "General Considerations" from the NAS 1974 edition of Recommended Dietary Allowances, which, of course, was not available to the agency when it promulgated the regulations.[38] Sample extracts from this are as follows:

> RDA are estimates of "acceptable daily nutrient intakes" in the sense that, although the needs of most individuals will be less than the RDA standard, there may be a small number who require more. . . . It is not possible to be more explicit about the relationship between RDA and the requirements of an individual; thus, it is only within the framework of statistical probability that RDA can be used legitimately and meaningfully.
>
> This has important implications. It means that such general statements as "RDA include a large safety factor; therefore a diet that meets two thirds of the RDA standard should be adequate" have no validity. It will be adequate for some, inadequate for others and—without elaborate studies—there is no way of knowing who falls into which category.

All the "appropriate uses" of the RDA's envisioned by the NAS involve evaluation of adequacy of food supplies or consumption patterns over a large population, and not for individuals. Thus, the categories of uses listed are "Planning and Procuring Food Supplies for Population Groups," "Interpretation of Food Consumption Records in Relation to Assessment of Nutritional Status," "Nutri-

38 Although the Government's brief says that the new edition "reduc[es] the RDA's for several nutrients," the publication makes a number of adjustments in each direction.

tional Allowances as Guidelines in Establishing Policy for Health and Welfare Programs," "Use of RDA in Nutritional Surveys and Their Relation to Government Policy," and "Nutrition Education." Only in a final category, "Product Development, Nutritional Labeling, and Regulation of Nutritional Quality," does the possibility of any kind of individual application emerge. And that possibility is confined to informational labeling and to the establishment of minimal levels of fortification for foods which lose nutritional value in processing.[39] By way of demonstrating that the RDA's are objectively inappropriate for uses other than these envisioned by the NAS, petitioners also emphasize that, on the basis of the FDA's own findings, RDA's provide an adequate intake of essential nutrients only for "essentially all of the normal healthy persons in the United States," more specifically 95% to 99% of the "normal healthy" population;[40] that even this 95-99% range is apparently derived by excluding certain needs which petitioners regard as nutritional but the FDA considers therapeutic (*e.g.*, increased needs for vitamins and/or minerals on the part of women taking oral contraceptives and persons who do not absorb vitamins well), and is derived by partially ignoring what is now a fairly widespread if minority belief that the "op-

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39 The further suggestion of the NAS at the very end of its discussion of "Product Development, Nutritional Labeling, and Regulation of Nutritional Quality" that "for new products that are not identified in any way with traditional products but which might become important sources of energy, RDA expressed per 100 kcal could provide a standard for nutritional formulation," and that this might include the setting of maxima per 100 kcal "to guard against possibility of hazardous excesses," is irrelevant to the products at issue in the current proceeding.

40 The record apparently contains no data showing how far these percentages might be increased as a result of the FDA's having set the maxima at generally 150% rather than 100% of the RDA's. Compare note 43 *infra*.

timal" level of nutrition considerably exceeds that necessary to avoid clinical deficiencies; and that the experimental and other methods for developing the RDA's are admittedly far from perfect and the state of current knowledge far from complete.

If the FDA had sought to prohibit ingestion of more than the maxima insofar as it could, even with the considerable safety factor arising from increasing the limit to 150%, which is superimposed upon the vitamins and minerals contained in the consumer's basic food diet, *see* note 37 *supra*, we should indeed have found it impossible to sustain the regulations.[41] But the agency has done nothing of the sort. Beyond the possibility that some application for relief from the upper limits will be granted pursuant to Part II of this opinion, anyone who is not satisfied with the quantity of a vitamin or mineral permitted in a combination or in a separate pill can take as many more tablets as he likes. He will doubtless find this more expensive, but, as previously suggested, *see* p. 5239 *supra*, the additional payment required in such cases had to be weighed by the agency against the savings from useless expenditures by purchasers of supplements containing far higher potencies than they require.[42] The percentage of the population, whatever it be, who even under accepted scientific doctrine require dosages in excess of the upper limits have a similar recourse. Expert testimony on the advisability of adopting the maxima, in this limited way, was conflicting. Although the opinions of

41 Indeed, we already have found it impossible, in significant part because of the limitations of the RDA's, to sustain § 125.1(h), classifying all vitamin and mineral products in dosages exceeding the upper limits of the U.S. RDA's as "drugs." *See* Part III *supra*.

42 The amount of increase in the cost to high-dosage consumers, with respect to commonly demanded dosages of a particular product, is one of the factors the agency may consider in evaluating applications for relief from individual upper limits pursuant to Part II of this opinion.

those experts who favored the maxima may seem to us somewhat the less thoroughly reasoned or at least the less thoroughly articulated, they were explicitly and not irrationally based on the fact that the RDA's are the best tool of their kind available and are subject to constant revision; resolution of the conflicting expert evidence was therefore for the agency. Indeed, since anyone who wishes is free to take dosages in excess of the maxima, these may readily be viewed as just a very pointed informational device—and therefore as an application of the RDA's which is explicitly approved, rather than effectively disapproved, by the NAS' new edition, and which is by no means unreasonable, however imperfect the state of current nutritional knowledge.

In short, we cannot fault the agency, procedural issues apart, for adopting upper limits, generally 150% of the U.S. RDA's, in its standard of identity.[43]

V. *Refusal to Allow Dr. Robinson to Cross-Examine Dr. Sebrell*

Section 701(e)(3) of the Food, Drug and Cosmetic Act is one of the relatively few federal regulatory statutes which require rules "to be made on the record after opportunity for an agency hearing" within the meaning of 5 U.S.C. § 553(c). See *United States* v. *Florida East Coast Ry. Co.*, 410 U.S. 224, 238 (1973). Instead of being governed by the rather lenient standards generally imposed by § 553 with respect to rulemaking, such cases are subject to 5 U.S.C. § 556, the same section which governs

43 There is nothing arbitrary or capricious, as petitioner in number 73-2824 suggests, in the agency's "arbitrarily" choosing a safety factor of 50% over the U.S. RDA rather than, say, 100% or 5%. An agency which must draw lines is certainly free to allow those affected a bit more leeway than it would be required to do on the basis of the evidence before it; it need not justify the precise amount.

adjudication. Subsection (d) of § 556 provides, *inter alia*, that

> [a] party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts.

During the presentation of the FDA's case, all parties were permitted liberal cross-examination.[44] However, after the opposition began to offer its evidence almost eighteen months after the hearing commenced, the Hearing Examiner, evidently concerned about the length of the proceeding, decided to limit the rights of Participants to cross-examine the witnesses called by other Participants. In an order dated December 24, 1969, the Hearing Examiner "concluded that said Participants are in opposition to the said Stayed Regulations and that witnesses offered by such Participants would not ordinarily be considered to be hostile to the opposition to the said Stayed Regulations of any other such Participant." If any Participant wished to cross-examine the witness of another, he was to serve a notice of intention to do so. The notice had to state that the written direct testimony of the witness was adverse to the interest of the Participant, make specific reference to the portion of the testimony considered to be adverse, and state the reasons therefor. The Hearing Examiner would determine whether to grant permission to

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44 The Hearing Examiner's pre-trial Hearing Conference Order No. 7, June 17, 1968, states generally that "the examination of witnesses shall be conducted in accordance with the practice generally accepted in American Jurisprudence and pursuant to the provisions of 5 U.S.C. Section 556 . . . ." More specifically, the order provided that, when a witness' "direct examination . . . has been completed, . . . he shall be cross-examined thereon by any participant desiring so to do . . . ." So liberal a rule not unexpectedly had its cost.

cross-examine in his discretion. If such permission were granted, the Participant's cross-examination was to be limited to those portions of the witness' written direct testimony specified in the notice. On its face this was fair enough. As the Committee Report on the APA indicated, "The provision [§ 556(d)] on its face does not confer a right of so-called 'unlimited' cross-examination. Presiding officers will have to make the necessary initial determination whether the cross-examination is pressed to unreasonable lengths." Sen. Doc. No. 248, 79th Cong., 2d Sess. 271 (1946). *See also,* 2 Davis, Administrative Law Treatise § 14.15 (1958); Hamilton, Rulemaking on a Record by the Food and Drug Administration, 50 Texas L. Rev. 1132, 1149 (1972).[45] The problem was created by the Hearing Examiner's application of the order in the case of a particularly important witness, Dr. William H. Sebrell, Jr., who had been Chairman of the Committee on Recommended Dietary Allowances of the Food and Nutrition Board of the National Academy of Sciences—National Research Council, the body which had prepared the 1968 RDA's whence the U.S. RDA's were drawn. The scientific validity of the RDA's was, of course, a question of central importance to the agency's promulgation of the regulations and to this Court's review of them.

Dr. Sebrell's name had been included in the FDA's list of witnesses in support of the proposed regulations. He was not called for the reason, as we were told at argument,

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45 Speaking of this very proceeding, Professor Hamilton said of the cross-examination during the FDA's case:

> [M]ost of the hearing consisted of repetitious and cumulative cross-examination of Government witnesses. Scientists and professional witnesses were asked to return on numerous occasions for additional cross-examination. One physician flatly refused to return; others, sensing a difficult and prolonged examination, simply declined to testify. Because the FDA has no subpoena power, the desired testimony was lost.

that he was unwilling to support all of the FDA's regulatory proposals.[46] However, this change of plan was not made known in advance to the Participants,[47] who had justifiably withheld cross-examination of other FDA witnesses because these witnesses had less personal knowledge of the process by which the RDA's were developed and, in many cases, testified before the final form of the 1968 RDA's were made public.[48]

One of the principal opponents of the regulations was Dr. Miles H. Robinson,[49] representing the National Health Federation (NHF). He had cross-examined the FDA

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46 In his written direct testimony, he announced disagreement with the wisdom of § 125.2(b), which proscribes six categories of statements about foods for special dietary use. *See* Part VI, *infra*.

47 Indeed the Participants were affirmatively, although we assume unintentionally, misled. Dr. Filer, an FDA witness, testified, when asked about the validity of the RDA's,

> We are cluttering up the record, taking my time and your time, to talk about something that is going to be changed, and has been changed . . . . Dr. Sebrell will be here one of these days.

FDA counsel Reilly emphasized that everyone should wait, saying,

> We intend to call Dr. Sebrell, who is the chairman . . . [of the body] that promulgated these [1968 RDA tables]. . . . [W]e will have to wait for the coming of Dr. Sebrell.

48 FDA experts Filer, Grollman, Boehne, Hodges, Gyorgy, and Olson were available for cross-examination before the 1968 RDA's were public. There would have been little point in cross-examining them closely as to the basis for RDA figures which were on the point of becoming obsolete.

49 That Dr. Robinson was caught by surprise by the sudden change in rules is apparent in the forcefulness of his objection to it:

> You have never denied this right to anyone before in this hearing. . . . You gave no notice of this. The precedent has been established that we would have the right to cross-examine these so-called friendly opponents . . . . There is no more frightening violation of justice than what you are about to do, Mr. Examiner. And I move that I be allowed to cross-examine this witness.

witnesses persistently, doubtless too persistently.[50] When Dr. Sebrell was ultimately called as a witness by the American Medical Association (AMA), Dr. Robinson served two notices of his desire to cross-examine Dr. Sebrell. It was explained to the Examiner that the interests of the NHF and the AMA were antithetical rather than identical, since the NHF was opposing substantially all the proposals, whereas the AMA was generally favorable, proposing only a few modifications.[51] The Examiner

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50 At one point, obviously exasperated by Dr. Robinson's persistence in cross-examination, the Hearing Examiner made perfectly clear his view of Dr. Robinson's efforts:

> Let me add one more word. Doctor, I have been extremely patient with you now for several months. If I arrive at the conviction that you are doing this deliberately and that it is your purpose to unduly extend this public hearing and in that way disrupt it and inconvenience all the people here involved I will not hesitate to exclude you. I am warning you.

51 In an argument to the Examiner, Dr. Robinson explained what he considered to be the contrariety of the positions of the NHF and the AMA:

> They are AMA witnesses, Mr. Examiner, and anybody with half an eye to see knows that the AMA wants these regulations to entrench its monopoly in the field of the practitioners of health. The chiropractors, Christian Scientist practitioners, and naturopaths, every practitioner not [approved] by the AMA uses these food supplements in his work. If these are barred and taken off the market in full variety and full potency the AMA's monopoly in the field of health is thereby further entrenched, and the . . . National Health Federation has known this for many years now.
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> Furthermore, Mr. Examiner, the AMA is against do-it-yourself treatment [with] high potency harmless vitamins. That competes with the AMA doctors that want people to come to their office and pay, pay well, pay $15 for the visit, pay up to 30 times as much for the vitamin on prescription. There is a deadly collusion here, Mr. Examiner, between certain elements in the AMA leadership and the 101 billion-dollar food industry. If you carry out your prohibition to stop me from cross-examining on this, you are aiding and abetting that collusion, Mr. Examiner.

While Dr. Robinson's rhetoric may have exaggerated the differences between the Participants, even the FDA acknowledges "that all non-government parties may not have been aligned in all respects." Brief

declined to permit Dr. Robinson to cross-examine Dr. Sebrell, although he did allow such examination by Mrs. Janie A. Meeter (one of a group of individual consumer opponents), counsel for pharmaceutical manufacturers and trade organization, and, of course, the FDA. The Examiner also denied permission to appeal his adverse ruling to the FDA. He later said he was standing by his ruling "so that we will have a clear-cut issue which can eventually be

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for Respondents at 80. Indeed, with regard to the Participant sponsoring Dr. Sebrell as a witness, the AMA, FDA counsel stated that "in large part they support the very type of regulation that we are issuing here and debating about." A disinterested observer of the proceeding was moved to note, "In connection with this limitation on cross-examination, the examiner tended to treat all opponents of the proposed regulations as having parallel interests and denied most requests to cross-examine, even in situations where the general positions of the two parties were clearly antagonistic . . . ." Hamilton, *supra*, note 45, at 1149.

The reasoning process by which the Hearing Examiner arrived at his conclusion that the Participants to the proceeding could be divided into but two groups—the FDA and all the others—for purposes of determining which Participants were to be deemed to have the requisite adverseness for cross-examination is tortured and bears out Professor Hamilton's observation that selection of so inexperienced a hearing examiner was "unfortunate." *Id.* at 1148. Since each non-FDA Participant was opposed to at least one part of the proposed regulations, reasoned the Hearing Examiner, all had a common interest—to oppose the adoption of the regulations as then written. It was perhaps his prior experience as a trial lawyer with the Government, suggests Professor Hamilton, that "tended to cause him to view the proceeding as a trial and the various parties to the proceeding as adversary litigants," *id.* at 1148, for in explaining his ruling on the cross-examination issue the Examiner noted that "the proponent is the Government, while the participants, as adversaries of the proponent, are now presenting their defense to the proposed regulations . . . . The fact that the defense is not a joint defense is a matter of choice by the participants. That choice—that is, to present their cases in defense severally—does not operate to somehow make them [adverse] to each other, and entitle them to the right to cross-examine each other's witnesses."

That the AMA and NHF did not work out a "common defense," however, was not a matter of "choice;" no such "common defense" was possible. Much trouble would have been avoided if the Hearing Examiner had recognized this obvious fact or if FDA counsel had tried to prevent him from falling into error.

determined by the courts." We must gratify his ill-chosen wish.

We recognize that a hearing examiner must be allowed, indeed encouraged, to take steps to avoid repetitious or aimless cross-examination, particularly in a rulemaking proceeding which had become so gargantuan as this. As the Administrative Conference has recommended, Recommendations and Reports of the Administrative Conference of the United States, vol. 2, Recommendation 71.7, ¶ D(3), at 46,

> If several participants with common interests desire to cross-examine a witness, the hearing examiner should encourage the participants to select a lead attorney or attorneys to conduct the cross-examination. In the absence of a showing of prejudice, participants with common interests should be grouped by the hearing examiner, and participants in a group should not be permitted to cross-examine witnesses called by other members of the group.

But here the NHF and the AMA clearly did not have "common interests"; the NHF was substantially as adverse to the AMA as it was to the FDA. Moreover, those who were permitted to cross-examine Dr. Sebrell either did not share common interests with NHF or were ineffective. Mr. Dym, counsel for the Pharmaceutical Manufacturers Association (PMA), cross-examined Dr. Sebrell after counsel for the FDA completed his cross-examination.[52]

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52 The FDA's cross-examination of Dr. Sebrell, a witness offered by a Participant whose interests, under the Hearing Examiner's scheme, were "adverse" to the FDA, was something short of aggressive. With respect to the crucial question of the scientific basis for the figures contained in the RDA tables, the FDA's cross-examination yielded only the following:

> Q. Now, Doctor, with respect to these tables . . ., generally, would you explain for us the method and rationale whereby you

As the Hearing Examiner noted, Mr. Dym's interest was limited "to develop[ing] with Dr. Sebrell aspects of the testimony which affected over-the-counter therapeutic preparations." Indeed, the interests of NHF and PMA were in many respects adverse.[53] Neither can the Examiner's ruling be defended on the basis that cross-examination by another consumer representative was allowed. Mrs. Meeter, a housewife, lacked the professional skills essential for effective cross-examination of Dr. Sebrell. Whereas Dr. Sebrell's expertise relating to the RDA's was what

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arrived at these figures? A. I believe this was explained fairly well in my direct testimony. These figures were derived from the recommended dietary allowances of the National Research Council, Nation Academy of Sciences . . . .

The direct testimony to which Dr. Sebrell referred was merely descriptive and conclusory:

Q. In your opinion, is the table [containing the 1968 RDA's] a suitable basis for a system of regulations of vitamin and mineral supplements, fortified foods, and other foods offered for special dietary use because of vitamin and mineral content? A. Yes.

Q. What is the basis for your opinion? A. Because it is the consensus of the best scientific opinion in this country. This document was prepared by about 15 subcommittees consisting of about 200 people. It was then approved and accepted by the entire Food and Nutrition Board.

The short of it is that at no time did the FDA attempt to go behind Dr. Sebrell's assertion of the prestige of the Board as a basis for adopting the RDA figures and ask harder questions about the basis for the figures in scientific fact.

53 Counsel for PMA noted generally that the division of Participants was "foolhardy," "inaccurate," and "tends to suggest that all parties other than the Government have similar interests, because the wording [in the Hearing Examiner's order of December 24, 1969] is 'other participants,' which suggests all other parties are in one basket with similar interests, which obviously is not the case." More specifically, Mr. Dym said that "it is obvious Dr. Robinson and his client and the client I represent are not united in interest in this proceeding." Indeed, the Hearing Examiner himself appears to have agreed with Mr. Dym's assessment in this respect.

greatly concerned NHF,[54] Mrs. Meeter concentrated mainly on the problems of excluded nutrients and special individual nutritional needs and even in those areas had a great deal of difficulty in framing questions that could survive the objections of FDA counsel. In 21 pages of transcript she obtained answers to fewer than ten distinct questions; objections were sustained as to at least a dozen

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54 The FDA suggests that Dr. Robinson's particular interest in cross-examining Dr. Sebrell was not apparent at the time to the Hearing Examiner. "[F]rom the record it is obvious that Dr. Robinson . . . simply desired to ask each and every witness to the proceeding repetitious questions . . . ." Brief for Respondent at 83. The Hearing Examiner's exercise of his discretion in refusing to allow Dr. Robinson to cross-examine Dr. Sebrell was reasonable, therefore, "since it is apparent that the cross-examination related to nothing more than argument on matters already sufficiently developed by the evidence." *Id.* at 86.

Aside from the fact that NHF served two notices (January 6, 1970, and January 20, 1970) of its intent to cross-examine Dr. Sebrell, each notice naming him individually, Dr. Robinson made very clear in oral argument that NHF regarded Dr. Sebrell's testimony to be of particular importance for sustaining the validity of the RDA tables:

> In more detail, Mr. Examiner, why this testimony is adverse to the interests of the National Health Federation, Dr. Sebrell has testified extensively on 125.1 which upholds the FDA position that there shall be no more variety and no greater potency allowed than these stayed orders provide. . . .
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> . . . [T]he main interest of the National Health Federation has been that the variety and potency of harmless vitamins not be restricted . . . . [Dr. Sebrell knows] a great deal . . . about how scientific the RDA's are. And we challenge the scientific nature of these RDA's, and we will argue that they are arbitrary . . . .

The FDA also suggests that Dr. Robinson's notices of intent to cross-examine were virtually identical for all witnesses and were therefore justifiably given routinely negative treatment. While certain patterns of language do recur in the notices, nevertheless Dr. Robinson did identify specific and differing parts of the testimony of each witness in his notices. They cannot be said to be identical in this important respect.

Moreover, the Hearing Examiner could hardly be heard to confess surprise at Dr. Robinson's special interest in Dr. Sebrell in view of the Examiner's own observation during Dr. Sebrell's testimony that "we are talking to a man who is one of the outstanding authorities in this country."

more and on four occasions the Examiner had to caution Mrs. Meeter about the drift of her questions. So far as concerned the RDA's she succeeded only in obtaining from Dr. Sebrell general statements that they were up-to-date, that they will be periodically revised, and that they are based upon the best available information. This is in sharp contrast to the skills of Dr. Robinson, whose "ability to ask scientific questions" was recognized early in the hearings by the Hearing Examiner. Of course the Examiner could have limited the time to be allowed Dr. Robinson for cross-examination or taken other means to control Dr. Robinson's persistence. But one must wonder at the brinksmanship that would imperil a hearing which had already lasted for some eighteen months and was to continue for almost five more by what the Examiner himself recognized to be an exclusionary ruling of dubious validity—even to the point of denying permission to appeal to the agency itself.[55]

A court reviewing an agency rulemaking determination, even when governed by 5 U.S.C. § 556, is naturally disinclined to order a remand for failure to allow cross-examination, particularly on a record as enormous as this. Apart from the point which most trial lawyers have learned, through sad experience, that early dreams of confounding experts by cross-examination usually are dreams indeed, the court wonders how much more there would have been for the agency to learn. But Dr. Sebrell

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55 The fact that the FDA ultimately upheld the Hearing Examiner scarcely shows it would have done so if the issue had been presented at a time when reversal would not have been so costly.

The practice of agency hearing of appeals from truly critical evidentiary rulings by hearing examiners appears to have worked admirably in the SEC and NLRB. *See* 17 C.F.R. §§ 201.12 (codification of SEC Rule XII(a)), 201.11(e)(1973); 29 C.F.R. §§ 102.26, 102.41 (1972); Gellhorn and Larsen, Interlocutory Appeal Procedures in Administrative Hearings, 70 Mich. L. Rev. 109, 119-24, 130-34 (1971).

was no ordinary witness.[56] The FDA had presented no other witness who was a member of the Food and Nutrition Board, which adopted the 1968 RDA's, except Dr. Bernard Schweigert, whose direct examination was limited by the FDA to nutrient losses which occur as a result of the processing, transportation, storage, and cooking of foods and to a proposed regulation dealing with food fortification to overcome any such losses.[57] When Dr. Robinson attempted to question Dr. Schweigert about the scientific validity of the scope of the RDA tables, the Hearing Examiner sustained the objection of FDA counsel that the question "is beyond the scope."[58] In contrast, Dr. Sebrell had been chairman of the committee that had prepared the RDA's and on his own account had made many changes in adapting the RDA's into the U.S. RDA's that were incorporated into the regulations; and his testimony is the sole authority cited in the findings for the validity

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56 Dr. Robinson had made this very clear. *See* note 54, *supra*. Counsel for petitioners in Nos. 73-2129 and 73-2166 also objected strenuously to being denied an opportunity to cross-examine Dr. Sebrell about the "rationale for the table prepared by" him. When counsel persisted in his objections, he was threatened with expulsion from the hearing room.

57 The fortification program was to appear in § 80.2, a section which is not a part of the regulations here at issue. According to Dr. Schweigert, the program envisioned fortification of some foods at levels between 25 and 100 percent of the RDA's.

58 In fact, Dr. Schweigert did give some testimony about the validity of pre-1968 RDA's for purposes of the food fortification program mentioned in note 57. He testified that those RDA's, if met by the diet, would provide adequate nutrition for the majority of the population and that their use as a foundation for a food fortification program was reasonable. It is thus arguable that there was some basis in his direct testimony for questions during cross-examination about the scientific validity of the pre-1968 RDA tables, though his direct testimony in this respect was limited to the relationship between the then-existing RDA's and a now defunct regulatory proposal for fortifying food. However, he was not permitted to respond to cross-examination questions about the validity of the tables.

of these derivations.[59] The only other Board members who testified (except for Dr. Schweigert) were called by other Participants, and were thus as unavailable for cross-examination by Dr. Robinson as was Dr. Sebrell himself.[60]

The FDA is now fertile with suggestions how Dr. Robinson could have overcome the Examiner's egregious error, *e.g.*, by calling Dr. Sebrell as his own witness. But apart from other problems, we are not to take so lightly the command of Congress, whether wise or not, that in a rule-making hearing governed by § 556 "a party is entitled . . .

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59 Dr. Sebrell's personal role in the development of the derivations is apparent in his testimony. With respect to a change in the recommended level of thiamin, he says that the change is necessary "since in my opinion the proposed quantities are a little bit too low for safety and the slight increase indicated more nearly meets the physiological need." In support of its finding (contained in Finding of Fact 36 for Part 80, 38 F.R. 20737 (1973), that the table incorporated into § 80.1(f)(1) "represents a reasonable and scientifically accurate adaptation" of the 1968 RDA's, the FDA cites only Dr. Sebrell's testimony. Similarly the findings (contained in Finding of Fact 19 for Part 80, 38 F.R. 20735 (1973)) that the Food and Nutrition Board's 1968 RDA's "should be used as the source of authentic and reliable information on which to base a standard of identity for dietary supplements" and that the U.S. RDA's "may reasonably be derived" from those 1968 figures rely entirely on the testimony of Dr. Sebrell. Finding of Fact 6 for Part 80, which lists ten essential minerals, relies only upon Dr. Sebrell's testimony. Dr. Sebrell is also cited with others in support of the following Findings: 4, 5, 11, 12, 14, 16, 17, 19 (Part 80, 38 F.R. 20734-35 (1973)); 7, 8, 9, 11, 13, 15, 44, 45 (Part 125, 38 F.R. 20713-15 (1973)). With respect to Part 125, Finding 12, listing the thirteen essential minerals, relies solely on Dr. Sebrell's testimony (38 F.R. 20713 (1973)).

To be sure, other FDA witnesses generally supported the validity of the RDA tables in the regulations, *see* Finding of Fact 9 (Part 125, 38 F.R. 20713 (1973)), but none had the personal experience of Dr. Sebrell upon which to base such an endorsement and some of the critical Findings could be supported only by Dr. Sebrell among the FDA's witnesses.

60 The other Board members who were witnesses were Dr. Darby, Dr. Hand, and Dr. Mueller. Dr. Robinson gave notice of intent to cross-examine all three because, in his view, their testimony supported the FDA's position on the RDA issue. His requests were turned down.

to conduct such cross-examination as may be required for a full and true disclosure of the facts." [61] The opponents of the regulations were entitled to probe into such important matters as how the RDA's were prepared,[62] whether those who prepared them had any biases that might affect their judgment,[63] what doubts they entertained, what inconsistencies there were,[64] and how far the formulators intended the RDA's to be applied for the purposes to which they have been put. It is no sufficient answer that this court now has a good deal of such information, particularly on the last point, in the General Observations to the 1974 edition, to which we have referred in Part IV, and has not considered this to require invalidation of the regulations. The question rather is whether there is a

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61 In the words of the Senate Committee, "To the extent that cross-examination is necessary to bring out the truth, the party should have it." Sen. Doc. No. 248, 79th Cong., 2d Sess. 209 (1946), quoted in 2 Davis, Administrative Law Treatise § 14.15, at 328 (1958).

62 Dr. Robert Harris, Emeritus Professor of Nutritional Biochemistry at the Massachusetts Institute of Technology, characterized the Food and Nutrition Board's efforts as guesswork. While Dr. Harris' view may be unduly harsh, our examination of the record has turned up not a single instance in which the scientific processes by which the RDA figures were developed were subject to searching examination.

63 Petitioners in No. 74-1055 assert that, because Dr. Sebrell was never under cross-examination by counsel for truly adverse Participants, his financial connections with the food industry (which arguably has an interest in lower RDA's) through the Nutrition Foundation, which is dominated, we are told, by food interests and which subsidizes certain expenses of the Food and Nutrition Board, could never be explored. Any bias on his part, say petitioners, thus remains undiscovered.

64 One apparent set of inconsistencies involves the number of minerals deemed to be "essential." With respect to Part 125, the FDA has determined that there are thirteen essential minerals, *see* Finding of Fact 12, 38 F.R. 20713 (1973); for purposes of Part 80, essential minerals "include" only ten, *see* Finding of Fact 6, 38 F.R. 20734 (1973). In both cases, the same testimony by Dr. Sebrell is cited. While there is no inherent inconsistency between the two findings, one might wonder why there should be a difference.

significant probability that vigorous cross-examination of Dr. Sebrell might have caused the agency to adopt regulations differing from those that it adopted or have provided a record that would have affected the judgment of a reviewing court on the question of sufficiency. Since we cannot say in good conscience that there is not,[65] we must, therefore, remand the case to the FDA with instructions to reopen the record for the limited purpose of permitting reasonable cross-examination of Dr. Sebrell (or, if he is not available, some other qualified member of the Board) by Dr. Robinson or counsel of some other similarly interested Participant.[66]

VI. *Label and Labeling Requirements*

We next consider the validity of portions of Part 125 not directly related to the problems heretofore discussed.

As earlier noted, several petitioners do not object to the basic requirement of § 125.3(a), that "the label shall bear a statement of the percentage of the U.S. RDA of

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65 It can be argued that, to borrow Mr. Justice Fortas' language in *NLRB* v. *Wyman-Gordon Co.*, 394 U.S. 759, 766-67 n.6 (1969), in a somewhat different context, "to remand would be an idle and useless formality" since realistically "there is not the slightest uncertainty as to the outcome. . . ." *See also* Timberg, Administrative Findings of Fact, 27 Wash. U.L.Q. 62, 69-70 (1941) (suggesting that the long run consequence of a decision to remand may be "the mechanical regurgitation of 'canned' findings on a subject as to which nobody can entertain any reasonable doubts concerning the [agency's] opinion."), quoted in 2 Davis, Administrative Law Treatise § 16.12, at 479. But we think it would be wrong for a reviewing court to condone so flagrant a violation of 5 U.S.C. § 556(d) as occurred here. *See NLRB* v. *Wyman-Gordon Co.*, *supra*, 394 U.S. at 780-83 (dissenting opinion of Mr. Justice Harlan). We simply cannot assume that if Dr. Sebrell's support of the 1968 RDA's had been shattered by vigorous cross-examination, however unlikely that may be, the FDA or we would reach the same result.

66 Such proceedings need not toll the filing and hearing of applications for exceptions under §80.1(b)(4), which we have directed in Part II. If the cross-examination of Dr. Sebrell should lead to a change in the regulations, this can be reflected in the decisions on such applications.

such vitamins and minerals, as set forth in § 125.1(b), supplied by such food when consumed in a specified quantity during a period of 1 day," to which we have referred at the beginning of Part IV. In any event we see no infirmity in it. Whatever objections there may be to the U.S. RDA's when used as a basis for prohibiting the sale as dietary supplements of products exceeding the upper limits—and we have sustained these only because of the blatantly erroneous restriction on the cross-examination of Dr. Sebrell, *see* Part V, *supra*—they have no such force when the U.S. RDA's are used simply as measuring rods to inform the consumer what he is getting.[67]

In contrast, there is a chorus of objections concerning the requirements of § 125.2(b) with respect to labeling which we set forth in the margin.[68]

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67 Indeed, as previously mentioned, the "General Considerations" to the 1974 edition of the NAS' Recommended Dietary Allowances, the very document so heavily relied upon by petitioners in attacking the use of the RDA's to set maxima, *see* Part IV *supra*, deems "appropriate" their use in "informative nutritional labeling."

68 A food which purports or is represented to be a food for special dietary use shall be deemed to be misbranded under sections 201(n), and 403(a) and (j) of the act (21 U.S.C. 321(n), 343(a) and (j)), if its labeling bears any statement, vignette, or other printed graphic matter that represents, suggests or implies:

(1) That the food, because of the presence or absence of certain vitamins and/or minerals, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom, except that the label may state that the food is a source of an essential nutrient and that this nutrient is important for good nurition and health, and except that this provision shall not apply to foods represented for use solely under medical supervision in the dietary management of specific diseases and disorders.

(2) That a balanced diet of ordinary foods cannot supply adequate amounts of nutrients.

(3) That the lack of optimum quality of a food, by reason of the soil on which that food is grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(4) That the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

The most general objecion is that § 403(j) authorizes the FDA only to prescribe contents for a "label," [69] whereas "labeling" is defined by § 201(m), 21 U.S.C. § 321(m), to mean "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." It could be strongly argued that the power to prescribe the contents of a label must include the power to prevent labeling that would destroy the label's integrity. However, it is unnecessary to decide whether § 125.2(b) could be supported on this ground since the FDA could and did draw on § 403(a), which provides that a food shall be misbranded "if its labeling is false or misleading in any particular." We therefore turn to the specific provisions of § 125.2(b).

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(5) That the food has dietary properties when such properties are of no significant value or need in human nutrition. Ingredients or products such as rutin, other bioflavonoids, para-amino-benzoic acid, inositol, and similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential to human nutrition may not be combined with vitamins and/or minerals, added to food labeled in accordance with this section, or otherwise used or represented in any way which states or implies nutritional benefit. Ingredients or products of this type may be marketed as individual products or mixtures thereof: *Provided* That the possibility of nutritional, dietary or therapeutic value is not stated or implied. Examples of false or misleading statements or implications are:

(i) Label statements to the effect that their need or usefulness in human nutrition has not been established.

(ii) Label statements which otherwise disclaim nutritional, dietary or therapeutic value.

(6) That a natural vitamin in a food is superior to an added or synthetic vitamin, or that there is a difference between vitamins naturally present and those that have been added.

38 F.R. 20718 (1973).

69 The Act defines "label" in § 201(k), 21 U.S.C. § 321(k): "The term 'label' means a display of written, printed, or graphic matter upon the immediate container of any article . . . ."

(1) We shall not tarry long over § 125.2(b)(1). The FDA marshalled evidence that past sales of dietary supplements have often involved highly questionable claims as to effectiveness in the prevention, cure, mitigation, and treatment of diseases and symptoms; that consumers of these products have been confused and misled by such claims; and that even more moderate claims of effectiveness have no scientific validity.

The FDA presented an impressive case, based largely on the records in seizure actions, of the exaggerated claims made on behalf of various vitamin and mineral products. "Golden 50 Tablets" were said by their sellers to give pep to the post-50 generation, to assist them in constipation problems, and even to enable them to withstand the noise of children! "Vitamins Concentrated Honey Alfa Tea" was said to be useful in connection with gout, ulcers, migraine, alcoholism, and bedwetting. "Catalyn" was said to give one resistance to overweight, underweight, dropsy, prostate enlargement, and St. Vitus' Dance. "Comfrey," derived from a vigorous plant, was said thereby to increase virility. And another substance was claimed to be adequate in the treatment, *inter alia*, of mental disorders, cretinism, and poor teeth.

Evidence of consumer confusion about the efficacy of vitamins and minerals in the prevention, cure, mitigation, and treatment of diseases and symptoms was also clear. Ironically, some of the most effective evidence was provided in the form of about 50,000 letters received by the FDA in protest against the proposed regulations, apparently as a result of a campaign by NHF, which showed that many people were taking dietary supplements to remedy ailments which their physicians had been unable to diagnose or cure and that some had been urged to do so by claims of therapeutic value made in the promotion of such supplements. There was also evidence that even

truthful claims, such as that vitamin C would prevent scurvy and that vitamin B_1 would prevent beriberi, were harmful and misleading.[70] It was difficult to imagine a person in the United States whose diet would give rise to scurvy, and beriberi, which has ordinarily resulted from a diet consisting almost exclusively of rice, is equally rare in the United States; yet the broadcasting of such claims might frighten consumers into purchasing dietary supplement products they did not need. Finally, there was ample expert testimony of lack of any scientific basis for promoting vitamins or minerals as useful in the prevention, cure, mitigation, or treatment of any "diseases" or symptoms except nutritional deficiencies themselves and of gross exaggeration of the extent of the latter.

Against all this, petitioners relied upon evidence that many persons failed to ingest adequate amounts of vitamins and minerals; that vitamin and mineral deficiencies were associated with many diseases and symptoms; that physicians are often unable to identify some of the milder forms of vitamin deficiencies; and that it was therefore reasonable for consumers to purchase dietary supplements as "insurance" against the deficiency maladies brought to their attention by past promotional efforts. Petitioners also take issue with the FDA's evidence of consumer confusion by attacking the competency of the witnesses presenting it.

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70 That truthful statements may have deceptive results and may therefore be proscribed is not new learning. Interpreting a predecessor statute of the Food, Drug and Cosmetic Act containing a provision deeming as misbranded any food "if the package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which . . . shall be false or misleading in any particular," the Supreme Court observed a half century ago that "deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false." *United States* v. *95 Barrels of Vinegar*, 265 U.S. 438, 443 (1924).

Taking petitioners' evidence in the light most favorable to them, it merely posed an issue and did not dictate a decision. Petitioners may still make some rather broad types of statements about the importance of essential nutrients of health.[71] While the FDA might have presented more convincing witnesses on the subject of consumer confusion, still the witnesses who testified gave sufficient testimony on this score. We hold that there was substantial evidence to support § 125.2(b)(1).

(2) Much of the attack on § 125.2(b)(2) is bottomed on reading it to say more than it does. This is notably true of petitioners' evidence that many Americans—careless eaters, the elderly, the poor, and persons enrolled in many weight-reducing programs—who *do not eat a balanced diet* are deficient in various nutrients. Nothing in the challenged regulation prevents a manufacturer from saying so.[72] The regulation was aimed rather at scare advertising typified by a drug store counter sign which proclaimed, "The physician is faced, more and more, with the problem of restoring proper combinations of vitamins and minerals to the devitalized foods of the nation." Such promotional techniques have been commonplace, as testimony and exhibits offered by the FDA amply demonstrate.

On the other hand, the portions of the record that have been presented to us[73] do not contain much evidence either

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71 Under the terms of the regulation, "the label may state that the food is a source of an essential nutrient and that this nutrient is important for good nutrition and health."

72 The FDA clearly acknowledges that persons who fail to eat a *balanced diet* for one reason or another may not ingest adequate amounts of some nutrients. Indeed, during the rulemaking process it modified § 125.2(b)(2) to take account of this fact. 38 F.R. 20711 (1973) ("To further clarify this prohibition, the phrase 'balanced diet' will be substituted for 'diet,' since it is obvious that an unbalanced or poor diet could be deficient in nutrients.")

73 Although our order of January 15, 1974, called for a deferred joint appendix pursuant to F.R.A.P. 30(c), the parties, without seeking our

to support or to controvert the FDA's conclusion that a balanced diet of ordinary foods *can* supply adequate amounts of nutrients.[74] Perhaps the strongest support for this conclusion is that it is a tautology; since nature admittedly furnishes all the needed nutrients, a diet of "ordinary foods" that does not provide them is not "balanced." Beyond that is the known fact that millions of Americans get along quite nicely without "dietary supplements."

Nevertheless we are obliged to fault § 125.2(b)(2) with respect to iron, for there was strong and uncontradicted evidence that it was very difficult for women of child-bearing age and for children to obtain an adequate supply of this even from a balanced diet.[75] On the remand we are

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advance approval, decided at the last moment to disregard our direction. We refused to approve their "agreement" in lieu of a joint appendix, directed them to file copies of the portions of the voluminous administrative record on which they intended to rely, and warned that we would not feel bound to search out other portions of the record (which has remained at the FDA office in Rockville, Maryland, for convenient use by all parties), although we reserved the right to do so. Among the portions of the record not furnished to us are pages cited by some petitioners to show that the food supply provides generally inadequate amounts of vitamin B6, folacin, and magnesium. If petitioners wished us to take account of these, they should have filed copies of the relevant pages as we directed.

74 The FDA's approach on this question was passive and seems to reflect the assumption that its conclusion must be taken as true until proven otherwise. *See* 38 F.R. 20710 (1973) ("No evidence, except for testimony which related to specific segments of the population, such as that contained in paragraph 45 of the Proposed Findings of Fact [relating to the iron needs of women and children, of which more *infra*], is contained in the Hearing Record to establish that a diet of ordinary foods cannot satisfy all nutrition needs.")

75 Indeed, the FDA made a finding of fact that "it is often impractical to supply the iron needs of adult women with conventional foods, and iron supplementation is often advisable. . . . In addition, the iron requirements of infancy and of the latter half of pregnancy are clearly in excess of what may be obtained from a conventional unfortified diet." 38 F.R. 20715 (1973).

directing, the FDA may either adduce further evidence on this point or, as might be preferable, insert a proper qualification in § 125.2(b)(2).

(3) This provision was likewise aimed at scare advertising, of which the record contains several examples. However, in view of the paucity of evidence that consumers have thereby been induced to purchase unnecessary dietary supplements, we shall examine whether the prohibited statement would be false.

The relevant findings of fact are as follows:

> 37. Scientifically it is inaccurate to state that the quality of soil in the United States causes abnormally low concentrations of vitamins or minerals in the food supply produced in this country.
>
> 38. There is no relationship between the vitamin content of foods and the chemical composition of the soil in which they are grown.

38 F.R. 20715 (1973). Our review of the record makes clear that there was substantial evidence to support finding 38 and so much of finding 37 as relates to vitamins. The case with respect to minerals is closer since one of the FDA's two witnesses cited in support of the validity of the statement contained in finding 37,[76] Dr. William Allaway, later conceded that iodine and selenium contents in crops vary with soil composition,[77] although iron con-

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76 The FDA's other witness, Dr. Victor Herbert, was never seriously shaken from his testimony that evidence compiled by the Department of Agriculture does not support any contention that a dietary deficiency in minerals may be the result of loss of nutritive values in foods as a consequence of the soil on which the food is grown and that persons making such claims are staking out a position "contrary to the vast body of literature."

77 This concession is supported by a number of other witnesses and by a proposed finding of the Hearing Examiner that soils in different parts of the United States are deficient in one or more nutrients and that a

tent does not, and agreed that the following statement on dietary supplement labeling would be reasonable: "Plants grown on boron deficient soil may be deficient in Carotene or pro-Vitamin A." However, such recondite exceptions, even if important in the context of the regulatory scheme proposed by the FDA,[78] would not seem to require us to invalidate § 125.2(b)(3) in view of the FDA's interpretation that the regulation would not prohibit "[a]ny truthful claims, supported by adequate scientific data, relating to the specific nutrient value of a product," but would only proscribe "unsupported generalization that there is *a general deficiency in the daily diet* because of soil in which the food was grown." 38 F.R. 20711 (1973) (emphasis added).[79] We therefore uphold § 125.2(b)(3) on the understanding that the FDA will apply it in that light.

(4) This provision was supported by findings which read as follows:

> 39. Mineral nutrients in foods are not significantly affected by storage, transportation, cooking, and other processing.
>
> 40. While some vitamins are susceptible to partial destruction through the effects of heat, light, oxidation, and other physical and chemical reactions . . . , loss of nutrients from the ordinary effects of cooking,

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soil deficient in iodine, selenium, or zinc would produce plants with lesser concentrations of these minerals. Proposed Finding of Fact 412.

78 It should be noted that the substances referred to are not seen as essential nutrients by the FDA.

79 Since, as the Hearing Examiner found, *see* note 77 *supra*, soil deficiency is very much a local matter and since most people eat foods grown in a variety of locales, it is difficult to believe that even a national patchwork of local areas with soils in varying degrees deficient in various minerals could give rise to a "general deficiency in the daily diet."

processing, transportation, and storage have not significantly impaired the nutritional quality of food in the United States. There is no need or scientific justification for recommending, for example, the routine use of dietary supplements of vitamins and minerals to offset losses that occur as a result of these processes.

41. It is reasonable to prohibit representation or suggestions in labeling, promotional material, or advertising of foods offered for special dietary use based on vitamin and mineral qualities, that imply that a dietary deficiency of vitamins or minerals exists or is threatened in the United States by virtue of loss of nutrients which [sic] occur from processing, transportation, storage, and cooking.

38 F.R. 20715 (1973).

The evidence that minerals in food are not affected by transportation, cooking, processing, and storage was clear and substantial. The case with respect to vitamins, however, was otherwise. FDA witness, Dr. Bernard Schweigert, testified that, while some vitamins are stable (vitamins D and K), others may be destroyed by oxidation during storage (vitamins A, C, and E), light (riboflavin), and heat (many B vitamins).[80] Consequently, if the regulation prohibited any statement that vitamins are not lost during the storage, transportation, processing, or cooking of a food, we could not sustain it.

Once again, however, petitioners read the regulatory proscription too broadly. The FDA has said that it is not the intent of this provision to "preclude factually supportable statements that certain losses [in nutrient content] may be due to improper handling;" the target is

80 Such losses can be quite substantial. Dr. Schweigert testified that cooking may reduce the levels of thiamin, pantothenic acid, and vitamin B_{12} by as much as 50 percent in foods.

rather the "unsupported generalization that there is a general deficiency in the daily diet because of . . . transportation, or processing methods used in preparing food." 38 F.R. 20711 (1973).

The important point in this connection is not whether certain foods may suffer important nutrient losses but whether the overall daily diet, consisting of a number of foods each with its own nutrient levels, is inadequate. The expert opinion of Dr. Olaf Mickelsen was that, while diets consisting solely of a food seriously deficient in nutrients can lead to nutritional disorders, the inclusion of the wide variety of foods normally found in the daily diet eliminated any significant danger. It is thus immaterial that, as one of the petitioners' witnesses testified, 60% of the vitamin C in snap beans is lost in transportation and refrigeration. No one lives on a diet of snap beans, and citrus fruits are rich in vitamin C.

(5) This prohibition presents a special problem in that, while the first and fourth sentences and the proviso, like all the other provisions in § 125.2(b), deal only with labeling, the second and third sentences are substantive in effect.

Basic to the validity of all parts of § 125.2(b)(5) is the question whether there is substantial evidence that the four named ingredients or products "are of no significant value or need in human nutrition." [81] Stated as such, the proposition is questionable as to some of the substances.[82] However, the FDA's real meaning is made clearer in finding 3:

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81 As to any ingredients other than the four named ones which the agency may mean to cover by the "such as" and "similar substances" language of § 125.2(b)(5), *see* note 31 *supra*.

82 In the absolute sense there is little question that some of the substances which may not be combined with essential nutrients are of significant value in human nutrition. There was evidence, for instance, that inositol "definitely" played "a significant role" in human nutrition.

> **Many dietary supplements include named ingredients *which are of no value as supplements to the human diet.***

38 F.R. 20713 (1973) (emphasis added). With respect to the four substances named in this provision, this proposition was supported by testimony that, even when such substances do play some role in nutrition, there was no known evidence of need for supplementation.[83] As to many others that have been included in dietary supplements there was no evidence of nutritional value at all. If subsequent research should show the need for such supplementation, the case would be appropriate for action under § 80.1(b)(4); if the standard of identity were modified to allow these as optional ingredients, § 125.2(b)(5) could not prohibit references to them in labeling.

With this much established, the validity of the first sentence of § 125.2(b)(5) requires little further discussion. There was ample evidence that labeling of dietary supplements making reference to include nonessential substances was misleading. The FDA found:

> 3. . . . [M]any consumers will purchase such products with long lists of ingredients, believing them to be of better value than products with a lesser number of ingredients. . . . Such consumers believe that if an ingredient is listed, it must significantly contribute to the value of the product as a dietary supplement.

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83 Inositol may reasonably be deemed nonessential because, according to the testimony of Dr. Olaf Mickelsen, even when persons were deprived of outside sources of it in an experiment, no inositol deficiency developed. The body is evidently capable of manufacturing its own supply of this substance. Similarly, biotin, a vitamin in the vitamin B group, was deemed nonessential because there is no known deficiency condition which could require supplementation by it.

22. The establishment of qualitative and quantitative limits on the composition of dietary supplements will reduce consumer confusion concerning choice of dietary supplements by ensuring a basically rational formula for all products.

38 F.R. 20713 (1973). The record contains substantial evidence to support this part of the provision.

While one would have predicted loud protest against the proviso in the third sentence, apparently there is no direct challenge. In any event, as evidenced by *United States* v. *An Article of Food . . . Labeled . . . Nuclomin*, 482 F.2d 581 (8 Cir. 1973) (where the product included inositol and part-amino-benzoic acid, two of the nonessential substances specifically mentioned in this provision) the FDA's experience had shown that disclaimers of value did not solve the problem of the misleading effect of including such ingredients in combinations. Thus the FDA could well conclude that in the sale of products consisting solely of such nonessential ingredients a disclaimer could have the effect of calling attention to the potential nutritional value of the product, and it could therefore proscribe such disclaimers as misleading.

This leaves the substantive provisions of the second and third sentences. Since the named substances are reasonably deemed nonessential and since the first sentence is valid, the second and third sentences are easily sustained, for the power to establish a reasonable standard of identity for dietary supplements necessarily includes the power to exclude from combinations ingredients that have not been shown to be useful for the purpose for which they are offered, even though they are harmless.[84]

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84 *Cf. United States* v. *An Article of Food . . . Labeled . . . Nuclomin*, *supra*, where the court noted, in connection with a dietary supplement portrayed by its manufacturer as harmless, "it is immaterial to a ques-

(6) Most of the argument over this prohibition stems from petitioners' reading into it language that is not there; they fear that the regulation would prohibit labeling that would merely disclose that the vitamin was natural and what its source was.[85] However, the Government's brief construes the regulation as prohibiting only "representations that a natural vitamin is *superior* to an added or synthetic vitamin, or that there is a difference between vitamins naturally present and those that have been added." Brief for Respondent at 44-45 (emphasis in original), and calls attention to a passage in the preamble to the regulations, 38 F.R. 20711 (1973), where the agency stated: "A factual and true statement of the origin of a nutrient is permitted, and only a claim of superiority is prohibited. This prohibition was included because of widespread claims that nutrients of natural origins are superior to synthetic nutrients." This is surely a permissible, indeed

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tion of misbranding [under § 403] whether the condemned article is inherently dangerous or harmful or whether it may in some way be beneficial." 482 F.2d at 585.

85 Counsel for National Nutritional Foods Association, Solgar Co., Inc., and National Association of Pharmaceutical Manufacturers fear that this provision "is so broad as to suggest that any statement in the labeling, other than a mere listing of the ingredients on the label of a vitamin product that it is made from natural sources, would constitute a prohibited claim, suggestion or implication that nautral vitamins are superior to synthetic vitamins." Their fears are perhaps understandable in light of finding 27:

> A large number of dietary supplements on our domestic market advertise or otherwise call attention to the claim that their ingredients are "natural" or derived from "natural sources."

which makes no reference to claims of superiority, and finding 28:

> More than half of the people in the United States are likely to choose foods for special dietary uses that contain ingredients described as "natural" or derived from "natural sources" in the belief that "natural" foods are superior to "synthetic foods."

38 F.R. 20714 (1973).

we think the only permissible, reading of the regulation. Since there was abundant evidence to sustain finding 26:

> There is no nutritional difference between a vitamin produced by a synthetic source and the same vitamin provided by a natural source, but the natural source may contain other ingredients which may limit the absorbability of the vitamin provided by the natural source.

20714 (1973),[86] we uphold this regulation.

The upshot is that we sustain § 125.2(b) in its entirety save for so much of § 125.2(b)(2) as prohibits appropriate statements about the adequacy of a balanced diet of ordinary foods to provide needed amounts of iron for women and children. On this the FDA on remand must either adduce additional probative evidence or include an appropriate qualification.

VII. *Fresh Fruits and Vegetables*

Sunkist Growers, Inc., petitioner in No. 73-2753, a cooperative of many citrus fruit growers in California and Arizona, complains in effect that *any* application of Part 80 to fresh fruits and vegetables, *see* § 80.1(e)(5), (6), *supra*, would contravene the two provisos of § 401 which we set out in the margin;[87] Sunkist also complains that the

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86 Some petitioners also argue that the source of vitamins is relevant for a consumer choosing among vitamin supplements because natural vitamins are often accompanied by other known nutrients or unidentified nutritional factors which may eventually be found useful in human nutrition. With respect to the independent nutritional importance of many such substances accompanying natural vitamins, however, Dr. Victor Herbert pointed out that those substances could as easily be harmful as beneficial. In any event, the regulatory proscription relates only to the value of the vitamin in and of itself.

87 *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards

definition of "special dietary use" in § 125.1(a), which we likewise set out in the margin,[88] is so broad as to include fresh fruits and vegetables, which, it is argued, would also be unauthorized, or at least arbitrary or capricious and thus violative of 5 U.S.C. § 706. On December 12, 1973, the Assistant General Counsel of the FDA wrote counsel for Sunkist, offering to stipulate that the regulations would not prevent advertising or labeling claims concerning vitamin or mineral content naturally occurring in fresh fruit or vegetables and would apply to such produce only in two eventualities.

One was that if vitamins or minerals were added to fresh fruits or vegetables so that the total level of any added vitamin or mineral per single serving (whatever that might be in the case of a vegetable) exceeded 50% of the U.S.

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of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons . . . . Any definition and standard of identity prescribed by the Secertary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

21 U.S.C. § 341.

88 (a) The term "special dietary use" as applied to food (including dietary supplements) used by man means a particular use for which an article purports or is represented to be used, including but not limited to the following:

(1) Supply a special dietary need that exists by reason of a physical, physiological, or other condition, including but not limited to the conditions of convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, diabetes mellitus, or the need to control the intake of sodium. The use of an artificial sweetener in a food, except when specifically and solely used for achieving a physical characteristic in the food which cannot be achieved with sugar or other nutritive sweetener, shall be considered a use for regulation of the intake of calories and available carbohydrate, or for use in the diets of diabetics.

(2) Supplying a vitamin, mineral, or other dietary property for use by man to supplement his diet by increasing the total dietary intake, except for foods for which nutrition labeling is used as required pursuant to § 1.17 of this chapter.

(3) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

RDA, *cf.* § 80.1(e)(5), *supra*, the product would be subject to Part 80. Since we cannot imagine natural produce, even as fortified, conforming to the standards of identity in that Part, the effect of this interpretation surely was to forbid such addition of vitamins or minerals to fresh fruits or vegetables offered for sale as foods. However, while the FDA could well have refrained from this refinement, we agree that such fabricated products are not within the intent of the provisos to § 401. Moreover, petitioner's grievance seems theoretical since there is no evidence that any such practice has occurred or is intended.

The other set of qualifications was this: If fresh fruits or vegetables were represented as dietary supplements of vitamins and/or minerals, *e.g.*, if oranges were sold as vitamin C supplements rather than with a simple statement that they are a source of vitamin C, Part 80 would apply, *cf.* § 80.1(e)(6), *supra;* again, we take it that the consequence of this interpretation—given that nature has not conformed oranges to the FDA's standard of identity—is that no such representation may be made with respect to fresh produce sold as foods. Also, if a fruit or vegetable were offered for sale for a particular dietary use, *e.g.*, if lemons were advertised as a source of flavoring for persons on low sodium diets, Part 125 (but apparently not Part 80) would apply.

We think all this goes too far. The first proviso to § 401 rules out any standard of identity for most fruits and vegetables, and the second permits this for citrus and several other fruits only as to maturity and the effects of freezing. Nothing indicates that the making of promotional claims, *e.g.*, that oranges are vitamin C supplements, should detract from the force of the provisos. And Part 125 simply does not fit fresh fruits and vegetables in their natural state. As petitioner says, the sheer variation in the content of oranges would seem to make compliance

with Part 125 impossible. On March 14, 1973, the FDA promulgated a new provision, § 1.17, *cf.* p. 5240 *supra*, dealing with food labeling, 38 F.R. 6951, 6959; but, on November 28, 1973, in response to an attack on § 1.17 in the United States District Court for the District of Columbia by Sunkist and another organization, Civ. No. 633-73 (complaint filed April 2, 1973), the agency exempted fresh fruits and vegetables pending further rulemaking, 38 F.R. 32786. We think that proceeding rather than this one is the proper place in which to deal with claims as to the value of fresh fruits or vegetables in their natural state as dietary supplements or to fulfill special dietary needs. We therefore enjoin enforcement of Parts 80 and 125 against them.

VIII. *Other Procedural Matters*

In this final section we deal briefly with a number of procedural objections in addition to the important one considered in Part V.

The most basic is the claim that the Hearing Examiner was appointed in violation of 5 U.S.C. §§ 3105 and 3344. These provide:

> § 3105. Appointment of hearing examiners.
>
> Each agency shall appoint as many hearing examiners as are necessary for proceedings required to be conducted in accordance with sections 556 and 557 of this title. Hearing examiners shall be assigned to cases in rotation so far as practicable, and may not perform duties inconsistent with their duties and responsibilities as hearing examiners.
>
> § 3344. Details; hearing examiners.
>
> An agency as defined by section 551 of this title which occasionally or temporarily is insufficiently staffed with hearing examiners appointed under sec-

> tion 3105 of this title may use hearing examiners selected by the Civil Service Commission from and with the consent of other agencies.

The contention is baseless, as was ruled six years ago in unreported opinion of Judge Tenney, *National Dietary Foods Association, Inc.* v. *Cohen*, No. 68 Civ. 2364 (S.D.N.Y., Aug. 29, 1968), with which we agree. When it became apparent in early 1967 that a lengthy hearing on the proposed regulations would be required, the FDA had only one hearing examiner, who was otherwise engaged. "Rotation" of hearing examiners for purposes of § 3105 was thus not "practicable." [89] The detailing of an examiner from another agency similarly was not feasible because the Civil Service Commission discouraged the borrowing of examiners from other agencies under 5 U.S.C. § 3344 where the hearing was expected to exceed six months.[90] With these statutory alternatives thus unavailable, the FDA determined that it was necessary to hire another hearing examiner on a more permanent basis. Accordingly, the FDA requested the Commission to certify a list of eligible candidates. Of the seven who were recommended, only two manifested interest; the FDA selected David A. Harris,[91] and his designation to hear this pro-

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89 The legislative purpose of the rotation requirement, to prevent "an agency from disfavoring an examiner by rendering him inactive," Sen. Doc. No. 248, 79th Cong., 2d Sess. 280 (1946), was in no way subverted by the FDA's action in selecting Examiner Harris.

90 *National Dietary Foods Association, Inc.* v. *Cohen*, *supra*, Memorandum Op. at 3. In view of the expected length of the proceeding, the FDA's staffing problem could hardly be called "temporary" within the meaning of § 3344. Moreover, even if the staffing need could be characterized as temporary, the language of § 3344 is permissive and not mandatory.

91 The contention of the National Health Federation that, in cases where rotation of hearing examiners within the agency is impossible, the Civil Service Commission and not the agency must select the examiner misses

ceeding was announced on April 2, 1968, 33 F.R. 5268 (1968). Since the other examiner was occupied, Mr. Harris' assignment complied with both the letter and the spirit of 5 U.S.C. § 3105.

Complaint is made that on several occasions the Commissioner of Food and Drugs and other FDA officials met with the Hearing Examiner without the presence of the parties or their counsel. The examiner prepared memoranda of these meetings, as well as of all other communications he had had with any party, and placed these in a public file. The memoranda show that the objective of the meetings with the Commissioner and other FDA officials was not to influence the examiner's decision on the merits but to get the protracted proceeding moving. The Hearing Examiner was directed to proceed expeditiously, hardly an unreasonable direction on its face, and petitioners make only conclusory allegations that such a direction had prejudicial effect upon them. It would scarcely have been practicable to invite all 104 participants to such meetings, although it might have been wise to secure the presence of a few representatives. We find no basis for reversal here.

A number of other challenges are made: that the Examiner invoked the provision of the APA, 5 U.S.C. § 556(d), which permits a requirement that direct testimony be submitted in written form, only after the FDA had finshed its own presentation; that he increased the number of hearing days from three to four per week and the closing hour from 4 to 5 p.m.; that some of his rulings on the admissibility of evidence prejudiced petitioners; that he displayed unwarranted hostility to Dr. Robinson and certain other representatives of petitioners; and that his policy of

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the point that § 3344 and the Civil Service Commission's role under it come into operation only when an examiner is to be borrowed temporarily from another agency. Such was not possible in this case.

not allowing Dr. Robinson to cross-examine witnesses of other Participants, *see* Part V, *supra*, deprived petitioners of their rights of confrontation with respect to witnesses in addition to Dr. Sebrell. The first three challenges, involving matters well within the Hearing Examiner's reasonable exercise of discretion, do not warrant discussion. It would have been better if the Examiner had shown more restraint with respect to petitioners' representatives, but their examination had been needlessly long and argumentative, *see* note 45, *supra*, and a reviewing court should not be overly critical of an examiner who had to preside over a hearing of this length. Finally, whatever may be said of the propriety of the restriction of cross-examination of witnesses other than Dr. Sebrell, petitioners have made no sufficient showing that this could have affected either the agency's action or our decision on review.

The petitions to review are granted in part and denied in part, enforcement of the regulations is stayed as provided in Part II, and the cause is remanded to the FDA for further proceedings consistent with this opinion. No costs.

APPENDIX B

OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT (OFFICIALLY REPORTED AT 491 F. 2D 1141 (2D CIR., 1973))

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

September Term, 1973.

(Submitted January 15, 1974 Decided February 1, 1974.)

Docket No. 73-2129

NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR CO., INC.,

Petitioners,

v.

FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH, EDUCATION AND WELFARE,

Respondent.

Before:

MOORE, FRIENDLY and ANDERSON,

Circuit Judges.

FRIENDLY, *Circuit Judge*:

This motion is made in one of fifteen petitions to review two orders of the Food and Drug Administration (FDA) signed by Alexander M. Schmidt, Commissioner of

Food and Drugs, on July 25, 1973, and published in the Federal Register on August 2, 1973. These orders added to 21 C.F.R. Part 80—Definitions and Standards of Identity for Food for Special Dietary Uses, 38 F.R. 20730-40, and revised Part 125—Label Statements Concerning Dietary Properties of Food Purporting to Be or Represented for Special Dietary Uses, 38 F.R. 20708-18. These voluminous regulations, fully effective December 31, 1974, are the end-product of a Notice of Proposal To Revise Regulations published in 1962, 27 F.R. 5815. The final phase began with a notice of public hearing in 1968, 33 F.R. 8679; the hearings lasted for almost two years and produced over 32,000 pages of testimony and thousands of pages of exhibits. Each set of regulations is preceded by several pages of comment (hereafter the preamble) in which the exceptions are summarized and reasons are given for their rejection or adoption. The petitions to review, filed in this Circuit and in the Ninth and District of Columbia Circuit, have all found their way to this court under 28 U.S.C. §2112(a) and have been consolidated.

The basis for the instant motion to take the deposition of Commissioner Schmidt and for related relief or to appoint a special master to achieve similar ends is as follows: Tentative final orders signed by Charles C. Edwards, then Commissioner of Food and Drugs, were published in January, 1973, 38 F.R. 2143-50, 2152-62; the time for filing exceptions expired on April 20, 1973. Meanwhile Commissioner Edwards had resigned. The formal exceptions spread over 1,000 pages; there were 20,000 additional letters. Commissioner Schmidt took office on July 12, 1973. During the 13-day period ending with the signing of the orders here under review, he signed and caused to be published 14 final regulations, 13 proposed regula-

tions and 6 notices stretching over many pages of the Federal Register, many of which deal with the composition or labelling of food products.[1] The final regulations here at issue contain a recital that the Commissioner had "considered the evidence received at the hearing, the hearing examiner's report, and all the exceptions and written arguments which were filed . . ." 38 F.R. at 20712; *see id.* at 20734. The relevant statute, 21 U.S.C. §371(e)(3), directs that after the prescribed procedures for hearing and objections, the Secretary of Health, Education and Welfare, whose powers have been delegated to the Commissioner of Food and Drugs, 21 C.F.R. §§2.68-2.98, "shall by order act upon such objections and make such order public."

In an effort to develop that it was physically impossible for the new Commissioner to have reviewed and considered the objections prior to signing the orders here at issue, the petitioners instituted an action against him in the District Court for the Southern District of New York. Judge Gurfein dismissed this for lack of jurisdiction. He noted that, as the parties agreed, under 21 U.S.C. §371(f) jurisdiction to review the orders lay in the courts of appeals. Plaintiffs contended, however, that a court of appeals could not take additional evidence before itself both because §371(f)(2) empowers the court of appeals, when a petitioner applies for leave to adduce additional evidence and makes a proper showing, only to

[1] Examples are Amino Acids in Food for Human Consumption, dated July 19, 1973, 38 F.R. 20036-39, and Standards of Quality for Foods for Which There Are No Standards of Identity, dated July 25, 1973, 38 F.R. 20726-30. Others deal with unrelated problems, e.g., Ch. 1, Part 273, Additional Standards for Source Plasma (Human) Used in Preparation of Blood Derivatives Intended for Injection, dated July 17, 1973, 38 F.R. 19362-68.

"order such additional evidence . . . to be taken before the Secretary" which would be manifestly inappropriate here, and because its collegial nature makes a court of appeals institutionally ill-adapted to take evidence itself. From the premise thus thought to be established, plaintiffs reasoned that, under §9(b) of the Administrative Procedure Act, now 5 U.S.C. §703, "the special statutory review proceeding" was inadequate for their immediate needs and an action lay in the district court. Judge Gurfein rejected both branches of plaintiffs' premise largely on the authority of *Braniff Airways, Inc.* v. *C.A.B.*, 379 F.2d 453 (D.C. Cir. 1967), where the court of appeals had obtained, apparently without objection, extra-record material relating to the internal processes of the Civil Aeronautics Board relevant to the claims of procedural irregularity raised before it. He further noted, with respect to the claim of institutional inadequacy on the part of the court of appeals, that this court could appoint a special master, citing a number of contempt proceedings for violations of orders of the Labor Board.[2]

The *Braniff* case may not be quite so authoritative as the district judge thought, since the Federal Aviation Act, 49 U.S.C. §1486, contains no express provision for the

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[2] The district judge stated that the only thing which gave him pause was a remark by the writer in *Toilet Goods Ass'n* v. *Gardner*, 360 F.2d 677, 684 n.8 (2 Cir. 1966), *aff'd*, 387 U.S. 158, 167 (1967), that in the review of rules "a district court may be in a better position than a court of appeals to carry out fact finding . . ." We agree that this afforded no ground for a different decision. The comment was made with respect to rules not protected by the usual provisions making findings supported by substantial evidence conclusive and limiting the production of new evidence. Both sides in the *Toilet Goods* case contemplated a trial if the Government's motion to dismiss were not granted.

taking of additional evidence, although it probably would be construed to require this to be taken before the Civil Aeronautics Board if taken at all. We nevertheless are in complete agreement with the court's rejection of petitioners' premise. The provision in 21 U.S.C. §371(f)(2) that additional evidence shall be taken before the Secretary refers to evidence that might alter his determination on the merits and for that reason should be taken before him—not to evidence that, because of procedural irregularity, his determination was a nullity. A reviewing court has inherent power to obtain evidence needed to enable it to decide a contention of this sort. The difficulties in a court of appeals' informing itself with respect to such a matter are imaginary. There is nothing to prevent the hearing of evidence by three judges, as sometimes occurs in courts convoked under 28 U.S.C. §§2281 and 2282, cumbersome though it be.[3] Apart from the possibility of appointing a special master, an alternate form of relief sought here by petitioners, the evidence desired could doubtless be obtained by deposition, as petitioners primarily propose. We thus entertain no doubt of our power to grant petitioners' motion.

Conceding that it is not the function of this court "to probe the mental processes" of the Commissioner, *Morgan* v. *United States*, 304 U.S. 1, 18 (1938) (*Morgan II*), petitioners insist they are entitled to probe whether he exercised his own mental processes at all. More particularly, they claim they are entitled to do this in a situation where

[3] Indeed evidence was taken before a court of three judges in *Morgan* v. *United States*, 23 F. Supp. 380 (W.D. Mo. 1937), after the remand in 298 U.S. 468 (1936), on which petitioners so heavily rely. It was done so again in the proceeding leading to *Morgan IV*, *see* 32 F. Supp. 546 (W.D. Mo. 1940).

two unusual and indisputable facts, namely, the short time between Commissioner Schmidt's assumption of office and his signing of the regulations here at issue, and the large number of other rules promulgated by him in the interval, create more than ordinary basis for doubt as to the extent of his personal reading and consideration.

It is plain enough that if this motion had come before us in the period between the first *Morgan* case, *Morgan* v. *United States*, 298 U.S. 468, 481 (1936), holding that in administrative proceedings "The one who decides must hear" and that a court seized of a review proceeding must inquire whether he had, and the fourth and last appearance of the *Morgan* case in the Supreme Court, *United States* v. *Morgan*, 313 U.S. 409 (1941), we would have been obliged to grant it. But the life of this aspect of *Morgan* I was extremely brief. In *Morgan IV* Mr. Justice Frankfurter, writing for a Court unanimous on this point,[4] took back most or all of what the first decision had given, 313 U.S. at 421-22. *Morgan IV* dealt with a proceeding wherein the Secretary of Agriculture had fixed rates for the Kansas City stockyards that would govern distribution of funds impounded during the long pendency of the litigation. Upon a challenge to the extent of the Secretary's participation in the making of these rates similar to that which had been made in *Morgan I*, the district court had taken his testimony as the Court had directed in *Morgan I*. After strongly suggesting that it would reject on the merits a challenge with respect to the degree of the Secretary's personal consideration, the Court went on

[4] Mr. Justice Roberts dissented on another issue. Chief Justice Hughes, the author of *Morgan I*, concurred in Mr. Justice Frankfurter's opinion.

to hold: "But the short of the business is that the Secretary should never have been subjected to this examination." 313 U.S. at 422. Professor Kenneth Culp Davis has correctly characterized this, 2 Administrative Law Treatise §11.05, at 59 (1958), as a return to the law declared in *De Cambra* v. *Rogers*, 189 U.S. 119, 122 (1903):

> It is hardly necessary to say that when a decision has been made by the Secretary of the Interior, courts will not entertain an inquiry as to the extent of his investigation and knowledge of the points decided, or as to the methods by which he reached his determination.

Subsequent Supreme Court decisions have not detracted from the force of *Morgan IV*. Petitioners rely on *United States ex rel. Accardi* v. *Shaughnessy*, 347 U.S. 260 (1954), *see also Shaughnessy* v. *United States ex rel. Accardi*, 349 U.S. 280 (1955), but the charge there thought to require the taking of evidence was that the agency to which discretion had been given, the Board of Immigration Appeals, had acted at the dictation of the Attorney General; indeed, the case is questionable authority for the taking of testimony even on its own facts. *See* 2 Davis, *supra*, §11.05, at 61 n.10. They press even more strongly a portion of Mr. Justice Marshall's opinion in *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 420 (1971), stating that on remand the district court "may require the administrative officials who participated in the decision to give testimony explaining their action." But *Overton Park* was a case where the Secretary of Transportation had made no formal findings; the taking of testimony, suggested as being within the range of proper action for the district court on remand, was for the purpose of

ascertaining why the highway construction had been authorized, a function performed by the extensive preambles to the regulations here at issue. The Court reaffirmed *Morgan IV*, saying that where findings accompany the decision, "there must be a strong showing of bad faith or improper behavior" before testimony with regard to reasons can be taken. *Id.* Indeed, the opinion went on to say that testimony might not be required even in *Overton Park* if the Secretary could prepare *post hoc* findings sufficient to withstand scrutiny. *Id.* at 420-21. Nothing in the opinion suggests that the Court intended to allow inquiry into the relative participation of the Secretary and his subordinates.[5] Similarly, strong preliminary showings of bad faith have been required in the court of appeals cases cited by petitioners before the taking of testimony has been permitted with regard to internal agency deliberations. *See, e.g., Singer Sewing Machine Co.* v. *NLRB*, 329 F.2d 200, 206-08 (4th Cir. 1964).

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[5] The difficulties of such an inquiry are illustrated by Mr. Justice Blackmun's concurrence, 401 U.S. at 422-23, pointing out that the case was "the end product of more than a decade of endeavor to solve the interstate highway problem at Memphis" and that the "administrative decisions under attack here are not those of a single Secretary; some were made by the present Secretary's predecessor and, before him, by the Department of Commerce's Bureau of Public Roads."

The statement in *Overton Park* that the district court could take testimony as to reasons was extended by *Camp* v. *Pitts*, 411 U.S. 138, 142-43 (1973) (*per curiam*), arising under the National Bank Act, from cases in which the agency has made no findings to those where its "stated justification for informal action does not provide an adequate basis for judicial review." *Id.* at 138. But *Pitts* no more than *Overton Park* suggests that inquiry will be permitted into relative participation in the decision by various agency personnel.

Appendix B

The facts of this case do not constitute nearly the showing of bad faith necessary to justify further inquiry; indeed they vividly illustrate the necessity of adhering to the presumption of regularity with respect to the participation of the officer authorized to sign administrative orders, especially in the context of the promulgation of legislative rules as distinguished from adjudication. As stated, the regulations here at issue are the end-product of more than a decade of work by the FDA. Petitioners do not contest that predecessors of Commissioner Schmidt, notably Commissioner Edwards, took an active part in the development of the regulations. All would have been well, apparently, if Commissioner Edwards had continued to serve. But because he resigned in April 1973 and Commissioner Schmidt did not take office until mid-July, promulgation must wait until the new Commissioner could personally familiarize himself with 1,000 pages of formal exceptions, 20,000 letters, and the staff's views about them, and read the relevant portions of the record (or summaries of them). And the same must be true of all the other regulations awaiting the new Commissioner's signature. With the enormous increase in delegation of lawmaking power which Congress has been obliged to make to agencies, both independent and in the executive branch, and in the complexity of life, government would become impossible if courts were to insist on anything of the sort. It would suffice under the circumstances that Commissioner Schmidt considered the summaries of the objections and of the answer contained in the elaborate preambles and conferred with his staff about them. There is no reason why he could not have done this even in the limited time available, *cf. Twin City Milk Producers Ass'n* v. *McNutt*, 122 F.2d 564, 568-69 (8 Cir. 1941); *Florida Economic Advisory Council* v. *F.P.C.*, 251 F.2d 643, 648 (D.C. Cir. 1957)

(Burger, *J.*), *cert. denied*, 356 U.S. 959 (1958), although we do not envy him the task.[6] In any event, absent the most powerful preliminary showing to the contrary, effective government requires us to presume that he did. It was his special insight into the workings of the administrative process, as it was and might become, that enabled Mr. Justice Frankfurter in *Morgan IV* to persuade the Court to retreat from *Morgan I*.[7] This is no time for an attempt to regain territory so wisely yielded.

The motion to take the testimony of the Commissioner and to have other discovery, or for the appointment of a master, is denied.

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[6] It should be noted that the demands on the Commissioner's time during the 13 days preceding the signing of these orders are somewhat exaggerated by the observation, stressed by petitioners and mentioned above, that in that period he signed and caused to be published 14 final regulations, 13 proposed regulations, and 6 notices. Although 21 U.S.C. § 371, for example, speaks in terms of action by the Secretary (and by delegation the Commissioner, 21 C.F.R. §§ 2.68-2.98) throughout the process of proposal and promulgation of many types of regulations with respect to food and drugs, nevertheless whatever remains of the *Morgan I* requirement that "The one who decides must hear" surely applies to the one who *ultimately* decides. Compare *Opp Cotton Mills, Inc.* v. *Administrator*, 312 U.S. 126, 152-53, *modified*, 312 U.S. 657 (1941). A spot check of the published items other than final regulations signed by Commissioner Schmidt between July 12 and July 25, 1973 reveals only the most limited assertions of a personal role. *See, e.g.*, Filled Milk Products: Proposed Common or Usual Name, dated July 25, 1973, 38 F.R. 20748-49; Ophthalmic Drugs Advisory Committee: Notice of Meeting, dated July 18, 1973, 38 F.R. 19850-51.

[7] Very shortly after *Morgan I*, a perceptive commentator had pointed out that, despite its seeming "so eminently reasonable on its face," the decision probably would require the Secretary of Agriculture "to devote all his time to the conduct of matters which must be considered petty from a national viewpoint." A. H. Feller, Prospectus for the Further Study of Federal Administrative Law, 47 Yale L.J. 647, 662 (1938).

APPENDIX C

FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED

DEFINITIONS

Sec. 201 [321].* For the purposes of this Act —

* * *

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

* * *

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

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* All bracketed references are to Title 21, United States Code.

Appendix C

PROHIBITED ACTS

Sec. 301 [331]. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

* * *

PENALTIES

Sec. 303 [333]. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine. . . .

* * *

DEFINITIONS AND STANDARDS FOR FOOD

Sec. 401 [341]. Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so

far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality and/or reasonable standards of fill of container: *Provided,* That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescibed by the Secretary for avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

* * *

Sec. 403 [343]. A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided,* That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as

may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as —

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided,* That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

* * *

REGULATIONS AND HEARINGS

Sec. 701 [371]. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) The Secretary of the Treasury and the Secretary of Health, Education, and Welfare shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health, Education, and Welfare shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) (1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406, 501(b), or 502(d) or (h) of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28, United States Code.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence, so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive [now covered by U.S.C. title 28, sec. 1254].

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

* * *

REGULATIONS UNDER REVIEW
38F.R.20717 (AUG. 2, 1973)

APPENDIX D

PART 125—LABEL STATEMENTS CONCERNING DIETARY PROPERTIES OF FOOD PURPORTING TO BE OR REPRESENTED FOR SPECIAL DIETARY USES

5. The provisions of §§ 125.1, 125.2, and 125.3 are revised to read as follows:

§ 125.1 Definitions and interpretations of terms.

The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable with the following additions:

(a) The term "special dietary use" as applied to food (including dietary supplements) used by man means a particular use for which an article purports or is represented to be used, including but not limited to the following:

(1) Supply a special dietary need that exists by reason of a physical, physiological, or other condition, including but not limited to the conditions of convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, diabetes mellitus, or the need to control the intake of sodium. The use of an artificial sweetener in a food, except when specifically and solely used for achieving a physical characteristic in the food which cannot be achieved with sugar or other nutritive sweetener, shall be considered a use for regulation of the intake of calories and available carbohydrate, or for use in the diets of diabetics.

(2) Supplying a vitamin, mineral, or other dietary property for use by man to supplement his diet by increasing the total dietary intake, except for foods for which nutrition labeling is used as required pursuant to § 1.17 of this chapter.

(3) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

(b) The term "U.S. Recommended Daily Allowance (U.S. RDA)" means the following daily amounts of the following vitamins and minerals:

Vitamins & minerals	Unit of measurement	Infants	Children under 4 years of age	Adults and children 4 or more years of age	Pregnant or lactating women
Vitamin A	International units	1,500	2,500	5,000	8,000
Vitamin D	do	400	400	400	400
Vitamin E	do	5	10	30	30
Vitamin C	Milligrams	35	40	60	60
Folic acid	do	0.1	0.2	0.4	0.8
Thiamine	do	0.5	0.7	1.5	1.5
Riboflavin	do	0.6	0.8	1.7	2.0
Niacin	do	8	9	20	20
Vitamin B_6	do	0.4	0.7	2.0	2.5
Vitamin B_{12}	Micrograms	2	3	6	8
Biotin	Milligrams	0.15	0.15	0.30	0.30
Pantothenic acid	do	3	3	10	10
Calcium	Grams	0.6	0.8	1.0	1.3
Phosphorus	do	0.5	0.8	1.0	1.3
Iodine	Micrograms	45	70	150	150
Iron	Milligrams	15	10	18	18
Magnesium	do	70	200	400	450
Copper	do	0.6	1.0	2.0	2.5
Zinc	do	5	8	15	15

[1] The following synonyms may be added in parentheses immediately following the name of the vitamin.

Vitamin	*Synonym*
Vitamin C	Ascorbic acid
Folic acid	Folacin
Riboflavin	Vitamin B_2
Thiamine	Vitamin B_1

(1) The U.S. Recommended Daily Allowances (U.S. RDA's) have been derived by the Food and Drug Administration from "Recommended Dietary Allowances", published by the Food and Nutrition Board, National Academy of Sciences-National Research Council, and are subject to amendment when new authentic and reliable information on human nutrient needs appears in new editions of the above publication.

(2) For determining the percentage of

the U.S. RDA's of vitamins in a quantity of food, as required in § 125.3(a), the quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

REFERENCE FORM

Vitamin	Name	Empirical formula	Molecular weight
Vitamin C	*L*-Ascorbic acid	$C_6H_8O_6$	176.12
Folic acid	Pteroyl mono-*L*-glutamic acid	$C_{19}H_{19}N_7O_6$	441.41
Niacin	Nicotinic acid	$C_6H_5NO_2$	123.11
Riboflavin	Riboflavin	$C_{17}H_{20}N_4O_6$	376.37
Thiamine	Thiamine chloride hydrochloride	$C_{12}H_{17}ClN_4OS.HCl$	337.28
Vitamin B_6	Pyridoxine	$C_8H_{11}NO_3$	169.18
Vitamin B_{12}	Cyanocobalamin	$C_{63}H_{88}CoN_{14}O_{14}P$	1,355.39
Biotin	*D*-Biotin	$C_{10}H_{16}N_2O_3S$	244.31
Pantothenic acid	*D*-Pantothenic acid	$C_9H_{17}NO_5$	219.24

(c) In addition to the vitamins and minerals listed in paragraph (b) of this section, vitamin K, choline, and the minerals chlorine, potassium, sodium, sulfur, fluorine, and manganese are recognized as essential in human nutrition, but no U.S. Recommended Daily Allowance (U.S. RDA) has been established for these nutrients. These nutrients are not appropriate for addition to general purpose foods or dietary supplements of vitamins and minerals but may be added to such other foods for special dietary use as infant formulas, and foods represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions.

(d) The term "artifical sweetener" means a sweetening substance not used in normal metabolism as a source of calories.

(e) The term "infant" means a person not more than 12 months of age.

(f) The term "serving" means that reasonable quantity of food suited for or practicable of consumption as part of a meal either by an adult male engaged in light physical activity, or by an infant or child when the article purports or is represented to be for infant feeding or child consumption. A label statement regarding a serving, as used in this part, shall be in terms of a convenient unit of such food or a convenient unit of measure that can be readily understood by purchasers of such food, e.g., a serving may be expresed in terms of slices, cookies, or wafers, or in terms of ounces, fluid ounces, teaspoonfuls, tablespoonfuls, or cupfuls. A teaspoonful shall be considered to mean 5 milliliters (approximately ⅙ fluid ounce) in volume; a tablespoonful shall be considered to mean 15 milliliters (approximately ½ fluid ounce) in volume; and a cupful shall be considered to mean 240 milliliters (approximately 8 fluid ounces) in volume.

(g) The term "diabetic" means a person having diabetes mellitus.

(h) Any product containing more than the upper limit of the U.S. RDA per serving (or, where appropriate, per daily recommended quantity) of a vitamin or mineral as specified in § 80.1(f)(1) of

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this chapter is a drug, except for conventional foods which contain naturally-occurring amounts in excess of these limits or which contain added amounts in excess of these limits pursuant to § 1.8(e) of this chapter so that it is not nutritionally inferior to the food for which it substitutes and which it resembles, and except as provided for in a specific regulation for such special dietary foods as infant formulas or foods which are represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions.

§ 125.2 General label statements: dietary properties; value; placement.

(a) If a food purports or is represented to be for any special dietary use, covered by other regulations, the principal display panel of its label shall bear a conspicuous statement of the usefulness of the food, limited to a listing of the dietary properties upon which such use is based: *Provided, however,* That if insufficient space is available on the principal display panel, the information panel may be used (21 CFR 1.8d), if such use is consistent with § 1.9 of this chapter. Such statement shall show the presence or absence of any substance, any alteration of the quantity or character of any constituent, and any other special dietary property of such food upon which such use is based.

(b) A food which purports or is represented to be a food for special dietary use shall be deemed to be misbranded under sections 201(n), and 403(a) and (j) of the act (21 U.S.C. 321(n), 343(a) and (j)), if its labeling bears any statement, vignette, or other printed graphic matter that represents, suggests or implies:

(1) That the food, because of the presence or absence of certain vitamins and/or minerals, is adequate or effective in the prevention, cure, mitigation, or

treatment of any disease or symptom, except that the label may state that the food is a source of an essential nutrient and that this nutrient is important for good nutrition and health, and except that this provision shall not apply to foods represented for use solely under medical supervision in the dietary management of specific diseases and disorders.

(2) That a balanced diet of ordinary foods cannot supply adequate amounts of nutrients.

(3) That the lack of optimum quality of a food, by reason of the soil on which that food is grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(4) That the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(5) That the food has dietary properties when such properties are of no significant value or need in human nutrition. Ingredients or products such as rutin, other bioflavonoids, para-aminobenzoic acid, inositol, and similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential to human nutrition may not be combined with vitamins and/or minerals, added to food labeled in accordance with this section, or otherwise used or represented in any way which states or implies nutritional benefit. Ingredients or products of this type may be marketed as individual products or mixtures thereof: *Provided*, That the possibility of nutritional, dietary or therapeutic value is not stated or implied. Examples of false or misleading statements or implications are:

(i) Label statments to the effect that their need or usefulness in human nutrition has not been established.

(ii) Label statements which otherwise disclaim nutritional, dietary or therapeutic value.

(6) That a natural vitamin in a food is superior to an added or synthetic vitamin, or that there is a difference between vitamins naturally present and those that have been added.

§ 125.3 Label statements relating to vitamins and minerals.

(a) If a food purports or is represented to be for special dietary use because of vitamin or mineral properties, the label shall bear a statement of the percentage of the U.S. RDA of such vitamins and minerals, as set forth in § 125.1(b), supplied by such food when consumed in a specified quantity during a period of 1 day. The quantity specified shall be a reasonable quantity suitable for and practicable of consumption within 1 day. The order in which the nutrients appear on the label shall be in the order listed in § 125.1(b), except when other regulations indicate otherwise. Immediately preceding the declaration of vitamin and mineral content, the following heading shall be stated, "Percentage of U.S. Recommended Daily Allowances (U.S. RDA)". If such purported or represented special dietary use is for persons within one or more groups for which the recommended daily allowance is set, such statement shall include the percentage for each age group. When such proportion or percentage is a whole number and a fraction or a whole number and a decimal, it shall be expressed as the whole number disregarding the fraction or decimal. The total quantity of vitamins or minerals in a food shall be no less than the amount declared, and no more than a reasonable amount above the declared quantity. Reasonable variations caused by heat, light, oxidation, storage, transportation, or unavoidable deviations in good manufacturing practice are recognized.

(b) The requirements of this section shall not apply to iodized salt, when the declared content of the iodine compound in the salt is equivalent to 0.01 percent by weight iodine.

Effective date. Labeling may be changed to comply with this regulation beginning on August 2, 1973. All labeling ordered after December 31, 1973, and all labeling used on products shipped in interstate commerce after December 31, 1974, shall comply with this regulation; *Provided*, That infant formulas and foods represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions shall not be subject to § 125.1(c) until a further FEDERAL REGISTER order so provides.

(Secs. 201(n), 401, 403(a) and (j), 701(a) and (e), 52 Stat. 1046, 1048, 1055, 1056, as amended by 70 Stat. 919; 21 U.S.C. 321(n), 341, 343(a) and (j), 371(a) and (e))

Dated: July 25, 1973.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

PART 80—DEFINITIONS AND STANDARDS OF IDENTITY FOR FOOD FOR SPECIAL DIETARY USES

§ 80.1 Dietary supplements of vitamins and minerals: definition, identity, label statements.

(a) The dietary supplements of vitamins and/or minerals for which definitions and standards of identity are prescribed by this section are prepared and offered as tablets, capsules, wafers, or other similar uniform units; in powder, granular, flake, or liquid form; or in the physical form of conventional foods; and purport to be or are represented for special dietary use by man to supplement his diet by increasing the total dietary intake of one or more of the essential vitamins and/or minerals specified in paragraph (f) of this section. The dietary supplements of vitamins and/or minerals are henceforth referred to as "dietary supplements" in this section.

(b) Classifications of dietary supplements.

(1) A dietary supplement shall contain only those vitamins and/or minerals listed in paragraph (f) of this section and shall be offered for its vitamin and/or mineral content only in the following combinations, with the provision that any vitamin or mineral defined as optional in paragraph (f) of this section may be omitted:

(i) All vitamins and minerals.

(ii) All vitamins.

(iii) All minerals.

(iv) All vitamins and the mineral iron.

(v) Inclusion of the optional ingredients vitamin D and/or phosphorus in a multivitamin, multimineral, or multivitamin and multimineral supplement does not require inclusion of any additional optional ingredients. Inclusion of the optional ingredients biotin and pan-

tothenic acid and/or copper and zinc in such products does not require inclusion of vitamin D and/or phosphorus when the latter two nutrients are optional. The inclusion of any of the other optional ingredients (biotin or pantothenic acid for vitamins and copper or zinc for minerals) requires the inclusion of both such optional ingredients if the product is a multivitamin or multimineral supplement, and requires the inclusion of all four such ingredients if the product is a multivitamin and multimineral supplement.

(2) A dietary supplement may also be composed of any single vitamin or mineral listed in paragraph (f) of this section.

(3) Folic acid is optional for liquid dietary supplements because of instability of the vitamin in liquid preparations. Liquid dietary supplements containing multivitamins but not containing folic acid shall bear the following statement on the label, "This product does not contain the essential vitamin folic acid" which shall immediately follow the listing of vitamins, and minerals as prescribed in paragraph (f) of this section.

(4) Addition to or amendment of the list of permissible combinations of vitamins and/or minerals contained in paragraph (b)(1) of this section may be proposed by the Commissioner of Food and Drugs, on his own initiative, or upon petition by an interested person in accordance with the procedures set forth in Part 2 of this chapter. Any such petition shall be submitted in the form set forth in § 2.65 of this chapter, and shall include scientific data of a human nutritional and/or technological nature to support such addition or amendment as being consistent with the definition and purpose of dietary supplements as described by this section. The Commissioner, upon request, may extend the effective date of this section with respect to any particular product or class of products pending consideration and any administrative or court proceedings relating to any such petition, and may set a new effective date upon completion of the matter.

(5) The provisions of this section shall not apply to any food which contains or consists of any vitamin or mineral listed in § 125.1(b) of this chapter, or any combination thereof, provided that all of the following requirements are met: (i) No such nutrient is contained at a level of 50 percent or more of the adult U.S. RDA per serving for that nutrient, (ii) No direct or implied representation is made on the label, in labeling, or in advertising that the product is a dietary supplement or is adequate or appropriate for supplementing the daily diet with essential nutrients, and (iii) The product is labeled pursuant to the provisions of § 1.17 of this chapter.

(c) General definitions.

(1) Subject to good manufacturing practices, dietary supplements described in this section shall contain in the specified daily quantity no less than the lower limit nor more than the upper limit of any nutrient specified in paragraph (f) of this section for the group(s) for which the supplement is offered.

(2) For the purposes of this section, the term "daily quantity" means the quantity of a dietary supplement that shall be specified in the labeling of the dietary supplement for consumption in a period of 1 day, and which shall be an amount or number of units reasonably suitable for and practicable of con-

sumption in 1 day.

(3) In the event a dietary supplement is offered for more than one specific group, the specified daily quantity for each group shall be stated separately on the label.

(d) The different groups described in § 125.1(b) of this chapter shall be designated as follows: For labeling purposes:

(1) Infants,

(2) Children under 4 years of age,

(3) Adults and children 4 or more years of age,

(4) Pregnant or lactating women.

(e) Section 80.1 does not apply to:

(1) Other standardized foods.

(2) Foods the composition of which is defined by other regulations or statutes.

(3) Any food represented for use as the sole item of a meal or of the diet.

(4) Foods represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions.

(5) Raw agricultural commodities (including marine products) and fabricated and other conventional foods to which single or multiple vitamins and/or minerals are added to improve nutritional quality, unless the total level (including any naturally occurring amounts) of any added vitamin or mineral per single serving attains or exceeds 50 percent of the U.S. Recommended Daily Allowance (U.S. RDA) for adults and children 4 years or more of age as specified in § 125.1(b) of this chapter, in which case the provisions of both this section and § 1.17 of this chapter shall apply. If the provisions of both this section and § 1.17 apply to a food, the labeling of such food shall conform to the labeling established in this section except that the labeling established in paragraph (c) of § 1.17 of this chapter, including the order for listing vitamins and minerals established in paragraph (c)(7)(iv) of that section, shall be used in lieu of the labeling established in paragraph (i)(1) of this section.

(6) Raw agricultural commodities (including marine products) which by their nature are sources of a specific vitamin(s) and/or mineral(s) at a level that, if it had been added, would have brought them within the definition of a dietary supplement. Such shall meet all the requirements of this section if they are represented as dietary supplements. Such foods may also be used as a source of specific vitamins and/or minerals in dietary supplements meeting the requirements of this section.

(7) A food with nutrients restored to pre-processing levels or added pursuant to § 1.8(e) of this chapter so that it is not nutritionally inferior to the food for which it substitutes and which it resembles.

(f) Permissible qualitative and quantitative composition of dietary supplements.

(1) The following table sets forth the permissible qualitative and quantitative composition of dietary supplements of vitamins and/or minerals:

U.S. GOVERNMENT RECOMMENDED DAILY ALLOWANCES (U.S. RDA's) AND PERMISSIBLE COMPOSITIONAL RANGES FOR DIETARY SUPPLEMENTS OF VITAMINS AND MINERALS

	Unit of Measurement	Children under 4 years of age [1]—U.S. RDA		Adults and children 4 or more years of age—U.S. RDA		Pregnant or lactating women—U.S. RDA	
		Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
Vitamins							
Mandatory							
Vitamin A	International Units	1,250	2,500	2,500	5,000	5,000	8,000
Vitamin D [2]	do	200	400	400		400	800
Vitamin E	do	5	10	15	30	45	30	30	60
Vitamin C	Milligrams	20	40	60	30	60	90	60	60	120
Folic acid [3]	do	0.1	0.2	0.3	0.2	0.4	0.4	0.4	0.8	0.8
Thiamine	do	0.35	0.70	1.05	0.75	1.50	2.25	1.50	1.70	3.00
Riboflavin	do	0.4	0.8	1.2	0.8	1.7	2.6	1.7	2.0	3.4
Niacin	do	4.5	9.0	13.5	10.0	20.0	30.0	20.0	20.0	40.0
Vitamin B [6]	do	0.35	0.70	1.05	1.00	2.00	3.00	2.00	2.50	4.00
Vitamin B [12]	Micrograms	1.5	3.0	4.5	3.0	6.0	9.0	6.0	8.0	12.0
Optional							
Vitamin D	International Units			200	400	400			
Biotin [4]	Milligrams	0.075	0.150	0.225	0.150	0.300	0.450	0.300	0.300	0.600
Pantothenic acid	do	2.5	5.0	7.5	5.0	10.0	15.0	10.0	10.0	20.0
Minerals Mandatory							
Calcium	Grams	0.125	0.800	1.200	0.125	1.000	1.500	0.125	1.300	2.000
Phosphorus [5]	Do	0.125	0.800	1.200	0.125	1.000	1.500			
Iodine	Micrograms	35	70	105	75	150	225	150	150	300
Iron	Milligrams	5	10	15	9	18	27	18	18	60
Magnesium	Do	40	200	300	100	400	600	100	450	800
Optional							
Phosphorus [6]	Grams							0.125	1.300	2.000
Copper	Milligrams	0.5	1.0	1.5	1.0	2.0	3.0	1.0	2.0	4.0
Zinc	Do	4.0	8.0	12.0	7.5	15.0	22.5	7.5	15.0	30.0

[1] When labeled for use by infants, a dietary supplement shall contain not less than the lower limit designated for a nutrient in this column nor more than 100% of the infant U.S. RDA for a nutrient as prescribed in §125.1(b) except that the level of biotin, when used, shall be 0.05 mg per daily recommended quantity.

[2] Optional for adults and children 4 or more years of age.

[3] Optional for liquid products.

[4] Lower limit may be 0.05 milligram until December 31, 1976.

[5] Optional for pregnant or lactating women. When present, the quantity of phosphorus may be no greater than the quantity of calcium.

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(2) The U.S. Recommended Daily Allowances (U.S. RDA's) have been derived by the Food and Drug Administration from the "Recommended Dietary Allowances," published by the Food and Nutrition Board, National Academy of Sciences—National Research Council, and are subject to amendment from time to time as more information on human nutrition becomes available.

(g) Acceptable ingredient sources for dietary supplements:

(1) A vitamin or mineral used in a dietary supplement may be supplied by any suitable chemically synthesized or naturally produced substance which is not a food additive as defined in section 201(s) of the act; or if it is a food additive as so defined, it shall be used in conformity with regulations established pursuant to section 409 of the act.

(2) Any safe and suitable substance may be used as a preservative, stabilizer, flavor, sweetener, color, seasoning, carrier, base, or vehicle, or to facilitate preparation of the vitamin and mineral substances. A dietary supplement shall be prepared so that any such substance contained therein does not exceed the amount reasonably required to accomplish its intended physical or technical effect, and so that the biological availability of the vitamin(s) or mineral(s) is not impaired by the presence of such substance. Any such substance shall not be a food additive or color additive as defined in section 201 (s) or (t) of the act; or if it is a food additive or color additive as so defined, it shall be used in conformity with regulations established pursuant to section 409 or 706 of the act.

(h) Nomenclature.

(1) The common name of a dietary supplement shall consist of a term descriptive of the vitamin and/or mineral composition of the product, as established in paragraph (h)(2) of this section, together with a phrase or phrases designating the group(s) for which the supplement is represented, as established in paragraph (h)(3) of this section (e.g., "multivitamin and multimineral supplement for children under 4 years of age"). The name of the dietary supplement shall appear prominently and conspicuously on the principal display panel(s) of the label. The letters of the phrase(s) designating the consumer group(s) for which the product is represented shall be no less than one-third the size of those used in the term descriptive of the composition of the product. In addition to the common name prescribed by this paragraph, a dietary supplement may be labeled with a proprietary name: *Provided*, That it is not false or misleading in any particular.

(2) The terms used to describe the vitamin and/or mineral composition of dietary supplements listed in paragraphs (b) (1) and (2) of this section shall be as follows: (i) "Multivitamin and multimineral supplement" for a dietary supplement containing all vitamins and minerals, (ii) "multivitamin supplement" for a dietary supplement containing all vitamins, (iii) "multimineral supplement" for a dietary supplement containing all minerals, (iv) "multivitamin and iron supplement" or "multivitamin supplement with iron" for a dietary supplement containing all vitamins and the mineral iron, (v) "———supplement" for a dietary supplement containing a single vitamin or mineral listed as a mandatory or optional ingredient in the table contained in paragraph (f)(1) of this section (the blank to be filled in with the name of the vitamin or mineral).

(3) The phrases used to designate the group(s) for which a dietary supplement is intended shall be as follows: (i) "For infants"; (ii) "For children under 4 years of age"; (iii) "For adults and children 4 or more years of age"; and (iv) "For pregnant or lactating women".

(i) Format for listing vitamins and minerals, and ingredients: (1) Immediately following the name and group designation on the principal display panel, as required by paragraph (h) of this section, or on the information panel (21 CFR 1.8d) if insufficient space is available on the principal display panel, the label shall bear a listing in tabular form of each of the vitamins and/or minerals supplied by the specified daily quantity of the dietary supplement, such daily quantity being specified at the top of the list. The vitamins and/or minerals shall be described by the names appearing in paragraph (f) of this section, shall appear in the order listed in paragraph (f) of this section, and shall be grouped and identified separately as "vitamins" and/or "minerals" without reference to "mandatory" or "optional." The quantity of each vitamin and/or mineral present in a specified daily quantity of the dietary supplement shall be stated as a part of this list and expressed in percentage of the U.S. RDA for each specific group for which the supplement is offered. The quantity of each vitamin and/or mineral present in the specified daily quantity of the dietary supplement shall also appear in the tabular listing in terms of the units of measure specified in paragraph (f) of this section.

(2) For determining the percentage contents of the U.S. RDA's present in the dietary supplement, the quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

REFERENCE FORM

Vitamin	Name	Empirical formula	Molecular weight
Vitamin C	*L*-Ascorbic acid	$C_6H_8O_6$	176.12
Folic acid	Pteroyl mono-*L*-glutamic acid	$C_{19}H_{19}N_7O_6$	441.41
Niacin	Nicotinic acid	$C_6H_5NO_2$	123.11
Riboflavin	Riboflavin	$C_{17}H_{20}N_4O_6$	376.37
Thiamine	Thiamine chloride hydrochloride	$C_{12}H_{17}ClN_4OS \cdot HCl$	337.28
Vitamin B_6	Pyridoxine	$C_8H_{11}NO_3$	169.18
Vitamin B_{12}	Cyanocobalamin	$C_{63}H_{88}CoN_{14}O_{14}P$	1,355.40
Biotin	*D*-Biotin	$C_{10}H_{16}N_2O_3S$	244.31
Pantothenic acid.	*D*-Pantothenic acid	$C_9H_{17}NO_5$	219.23

(3) The following synonyms may be added in parentheses immediately following the name of the vitamin in the statement described in paragraph (i) (1) of this section:

Vitamin	*Synonym*
Vitamin C	Ascorbic acid.
Folic acid	Folacin.
Riboflavin	Vitamin B_2.
Thiamine	Vitamin B_1.

(4) A separate list of ingredients in the product shall be included on the label pursuant to the requirements of Part 1 of this chapter. Such list shall include the natural source or chemical form of each individual nutrient present in the dietary supplement.

(j) When the dietary supplement is in liquid form and contains alcohol, the label shall state the percent-by-volume of alcohol present.

(k) A dietary supplement containing one or more nutrients, subject to deterioration below the labeled value before consumption shall bear on its outside wrapper or container, as well as on the label of its immediate container, the statement: "Expiration date ———", the blank to be filled in by the month and year. The expiration date shall be the date selected by the manufacturer, packer, or distributor of the dietary supplement on the basis of tests or other information showing that the dietary supplement, until that date, under the conditions of handling, storage, and use prescribed by directions appearing on its label, or, in the absence of such prescribed directions, under customary or usual conditions of handling, storage, and use will contain not less than the quantity of each vitamin and/or mineral as set forth on its label, when consumed.

(l) All labeling information required by this section shall comply with the conspicuousness required by section 403(f) of the act and § 1.8d of this chapter. In addition, the following labeling requirements shall be met.

(1) The list of nutrients required by paragraph (i)(1) of this section shall appear in uniform type size.

(2) The synonyms permitted by paragraph (i)(3) of this section, if used, and the list of ingredients required by paragraph (i)(4) of this section shall appear in uniform type size, and in type size no larger than that used for the list of nutrients required by paragraph (i)(1) of this section.

(m) In addition to the requirements of this section, the labels and labeling for a dietary supplement is subject to the prohibitions contained in § 125.2(b) of this chapter.

Effective date. Labeling may be changed to comply with this regulation beginning August 2, 1973. All labeling for dietary supplements that is ordered after

December 31, 1973, and all labeling used for such products shipped in interstate commerce after December 31, 1974, shall comply with the provisions of this section; and if not so labeled, such product shall be deemed to be misbranded under section 403(a), (g) and (j) of the act.

(Secs. 201(n), 401, 403(a) and (j), 701(a) and (e), 52 Stat. 1046, 1048, 1055–1056, as amended by 70 Stat. 919; 21 U.S.C. 321(n), 341, 343(a) and (j), 371(a) and (e))

Dated: July 25, 1973.

A. M. SCHMIDT,
Commissioner of Food and Drugs.